SMARTABLATE™ SYSTEM

RF Generator User Manual

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Preface

The SmartAblate™ Radiofrequency (RF) Generator is a highly specialized device intended for use during RF ablation therapy of the human heart. This device is used in conjunction with specialized therapeutic catheters and a dispersive pad (indifferent electrode) to create a closed electrical circuit capable of delivering specified doses of RF energy. The RF energy is delivered to cardiac tissue that forms unwanted electrical pathways that either drive or maintain arrhythmias. The RF energy heats the tissue such that it becomes denatured and no longer functional. This interrupts and/or destroys the unwanted electrical pathways, thereby restoring normal heart function.

The SmartAblate™ RF Generator actively generates specified doses of RF energy and continuously monitors, displays, and coordinates the amount of RF energy, the temperature of the catheter's ablation electrode, and the tissue impedance during ablation therapy. The temperature of the catheter's ablation electrode is measured by a sensor in the electrode and is transmitted to the generator. Simultaneously, high resolution impedance measurement circuits built into the generator measure the heart tissue impedance allowing detection of small tissue changes prior to, during, and after treatment. Before and during treatment, electrical signals generated by the heart are also detected and transmitted by the catheter through the generator to connected monitoring instruments. These signals in combination with the temperature of the ablation electrode, tissue impedance, and RF energy information are used by the operator to control the safe delivery of RF energy to locations within the heart that require treatment.

The SmartAblate™ RF Generator was designed to ensure simple, intuitive, and user-friendly operation. This device features a touch screen for making selections and setting parameters. Among the features of the screen is a display that shows power, temperature, and impedance in color-coded, real-time, continuous graphics during ablation. The generator features redundant protection circuits (if one safety mechanism fails, a second safety mechanism indicates the failure to ensure safety). Critical safety functions are controlled by buttons that are operated independently of the touch screen. A prominent red **Stop** button has priority over all other functions and connected devices, thus immediately stopping RF energy delivery when pressed.

The SmartAblate™ RF Generator is connected to the SmartAblate™ Irrigation Pump by a communication interface that allows both devices to be controlled from the user interface of the generator. If an error occurs in either of these devices, the necessary notification and recovery steps are initiated simultaneously in both devices.

This user manual describes the operation of the SmartAblate™ RF Generator. It is important that the user understand the functional principles of various methods of applying RF energy and the principles of power and temperature control that are presented in this manual. Proper application of RF energy leads to desired tissue denaturation to correct arrhythmias; incorrect application of RF energy can lead to excessive tissue denaturation.

The SmartAblate™ RF Generator may be used only by medical personnel trained and experienced in the techniques of electrophysiology. Before using this generator for the first time in a clinical application, the user should thoroughly read this user manual. To become familiar with operation of the generator and to avoid damaging it, the user should practice using the generator and all accessories by simulating ablation in a container of saline solution or by using a STOCKERT test box for the SmartAblate™ RF Generator. The user should also become familiar with all accessories and other devices connected to the generator by reading and following the instructions for use for the accessories and devices. For information on training and a STOCKERT test box for the SmartAblate™ RF Generator, please contact Biosense Webster.

We will gladly answer any questions that you may have.

Yours truly,

STOCKERT GmbH

1 Functional Principles

1.1 Functional Principles of RF Ablation

Cardiac RF ablation is the destruction of the electro-mechanical function (heart beat conduction) of cardiac tissue through the application of RF energy.

The term "radiofrequency" (RF) is used to refer to an alternating current that flows through a conductor. In the case of ablation, RF current flows through biological tissue that contains free ions. The saline solution present in the tissue provides the electrical conductivity. The tissue conductivity can be represented by the tissue impedance. Low impedance represents high conductivity and high impedance represents low conductivity.

The application of RF current to biological tissue causes heating of the tissue. The higher the RF current density in the biological tissue (current per unit area), the higher the resulting temperature. The tissue stops reacting to electrical stimulation when heated above a threshold over a minimal period of time.

The extent of heating is proportional to the RF power (current density) output. A low RF power output causes slow heating to the tissue (see Figure 1).

Figure 1

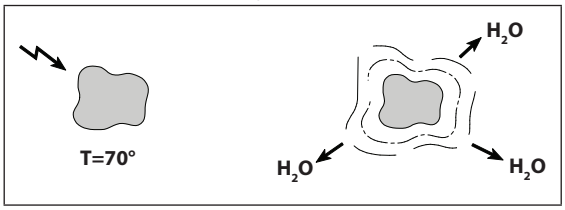
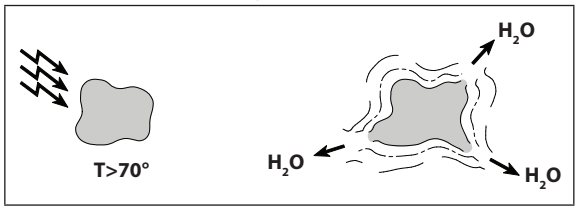


Figure 2



At high RF power output, the tissue can heat rapidly. Excessively high RF power output can overheat the tissue, causing evaporation of the water bound in the tissue (see Figure 2). This can result in charring of the tissue. Therefore, excessively high RF power output is not recommended. Charring reduces the energy delivery to the heart tissue, which can cause other side effects such as thrombosis or adhesions on the ablation electrode. It is recommended that ablation be performed using a moderate effective RF power setting.

A lesion (conversion of the soluble protein in the tissue into a denatured, coagulated state) arises when the tissue is exposed to RF current densities. At low current densities, the tissue is heated slowly and contracts as a result of fluid loss. When the tissue is exposed to excessively high RF current densities, the tissue fluid evaporates so rapidly that the resulting steam pressure in the cells destroys the cell membrane. If this process occurs suddenly (superheating), it is perceptible as a steam explosion. Since this phenomenon is audible in certain cases and under some circumstances can be felt at the catheter handle, it is also known as "pop." In extreme cases, this can lead to undesirable tissue changes such as tears, craters, and holes. A suitable choice of RF energy output and sufficient contact between the ablation electrode and the myocardial wall avoids this pop effect.

1.2 Power Controlled Ablation Method

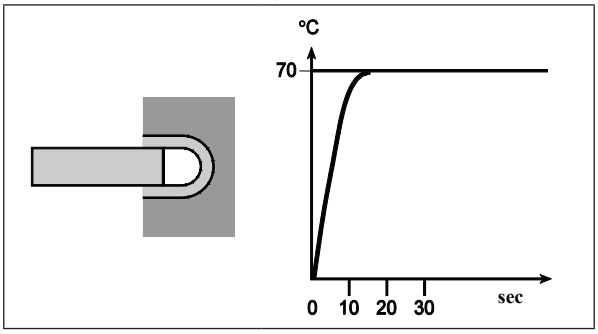
As described in Section 1.1, Functional Principles of RF Ablation, a high RF current can rapidly heat the tissue. With the power controlled ablation method, the RF power output can be manually adjusted on the basis of values known from experience.

The power adjusted by the user in this mode is the power output from the generator. The user should be aware that the lesion formation is dependent on the RF current density in the specific location in the tissue. This current density is a factor not only of the generator output, but also of the ablation electrode surface area and the contact between the ablation electrode and the cardiac tissue. In order to assess the effect of the RF power, the user must watch for intracardiac ECG signal reduction in the area of the ablation.

1.3 Temperature Controlled Ablation Method

The temperature of the ablation electrode is measured by a temperature sensor. In the case of non-irrigated ablation catheters, the temperature of the ablation electrode is an indication of the temperature of the tissue in contact with the electrode. During temperature controlled ablation, the RF power output is regulated automatically by the generator so that the temperature selected by the user is reached and maintained at the desired level (see Figure 3). Thus the risk of charring, tissue adhesion, or pop is greatly reduced.

Figure 3



The size of a lesion is determined primarily by the ablation time and temperature. With the temperature controlled ablation method, it is not necessary to set the initial RF power level manually.

Note: Because the ablation electrode measures only the temperature of the electrode with its integrated temperature sensor and not the actual tissue temperature deep inside the myocardium, tissue overheating can still occur. Therefore, temperature measurement is suitable only for limiting overheating. However, in some physical circumstances, temperature measurement may not prevent overheating. The temperature indicator is a guide, not an absolute measurement.

The difference between actual tissue temperature and the temperature measured by the integrated temperature sensor, moreover, depends greatly on the relevant catheter technology. When standard catheters that are not irrigated are used, the deviation in temperature is proportional to the electrode size (due to passive cooling by blood flow). The larger the ablation electrode, the larger the temperature difference. Regardless of the electrode used, the actual tissue temperature is the same as or higher than the indicated temperature. When an actively cooled ablation electrode is used (for example, an irrigated electrode cooled with saline solution), the electrode no longer provides a basis for accurate tissue temperature. In this case, the temperature measurement is an indicator of the irrigation function and is completely dissociated from the tissue temperature.

1.4 Unipolar Application Method

To perform ablation with RF current, a closed circuit is required. The RF current flows from the generator via the connection cable to the catheter's ablation electrode (tip electrode). The current then passes through the biological tissue and is passed back to the generator through a second electrode (indifferent electrode). In order for the tissue heating to occur at only the interface between the ablation electrode and the tissue, the second electrode must have a considerably larger surface area than the ablation electrode. This arrangement is known as a unipolar application.

Because the current density is highest at the smaller ablation electrode, most of the RF energy is converted into heat in the area of this electrode. The second, considerably larger RF electrode, is preferably a skin-adhesive electrode. This second electrode is known as an indifferent electrode or a neutral electrode. For safety reasons, care must be taken to ensure that the area of the indifferent electrode is considerably larger than the area of the ablation electrode. If the ratio between the electrodes is too small, severe skin burns can occur at the site of the indifferent electrode. With this type of application, the information provided by the manufacturer of the indifferent electrode and the information in Chapter 3, Warnings and Precautions, must be heeded.

1.5 Measuring Impedance

Measurement of tissue impedance (the electrical resistance in the tissue) is used for two purposes:

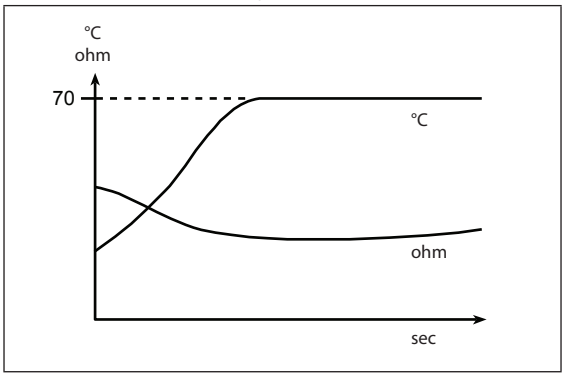
1. To differentiate between the various types of tissue so that the ablation electrode can be positioned correctly.

2. To confirm that a lesion is being formed during RF current application.

The SmartAblate™ RF Generator measures impedance between the surface of the ablation electrode and the indifferent electrode.

RF heating of the tissue changes the impedance because of the heating and dehydration of the tissue. During the increase in tissue temperature, the tissue impedance first falls to a minimum value and remains at this level for some time. Then the impedance rises based on the supplied power (see Figure 4). Impedance should be monitored during ablation. A rapid increase in impedance is an indicator that there is a problem and ablation should be stopped. One possible cause for the rapid increase is char formation; another possible cause is that the electrode has become buried in the tissue.

Figure 4



2 Indications

The use of the SmartAblate™ RF Generator and all accessories is indicated in combination with compatible therapeutic catheters for use in conventional intracardiac RF ablation procedures. Read and follow the instructions for use that are provided in this user manual before using the system in a clinical application. Also refer to instructions for use that are supplied with the accessories and with the compatible therapeutic catheters.

3 Warnings and Precautions

3.1 Warnings: Generator Usage

1. Read this user manual carefully before using the SmartAblate™ RF Generator for the first time. Note especially the instructions in Section 4.5, Setup.

2. Cardiac ablation procedures should be performed only by physicians who have been thoroughly trained in RF catheter ablation techniques. Catheter ablations should be performed only in medical rooms in compliance with IEC/EC 60601-1, Annex A.4, Clause 16.

3. In catheter ablation procedures, fluoroscopy is commonly used. When using fluoroscopy, there is the risk of exposure to considerable radiation. The intensity of the X-rays and the duration of the radiation can lead to acute radiation damage or to an increased risk of a physical or genetic defects for both patients and medical personnel. Therefore, perform catheter ablations only after carefully considering the potential radiation dose. The advantages and disadvantages of X-ray exposure should be considered carefully before catheter ablation is performed in pregnant women. Also, the long-term risk of prolonged X-ray imaging has not been researched. Therefore, the advantages and disadvantages should be considered carefully before this procedure is performed in prepubertal children. Consider using a navigation system without fluoroscopy to reduce exposure to X-rays.

4. Do not apply RF energy while a stimulator is connected to the generator unless specifically indicated by the stimulator's instructions for use. Doing so might induce ventricular fibrillation.

5. Always verify that the generator's visual and acoustic alarms are working before using the generator (see Section 6.1.1, System Startup).

6. When the generator has been turned off, power continues to be supplied to the generator through the mains cable. To completely cut off power to the generator, disconnect the mains cable from the generator. To allow easy disconnection in the event of severe power failure, make sure that the generator is located where there is easy access to the mains cable on the back of the generator.

7. After turning on the generator, always wait until the automatic self test has been successfully completed before starting the first steps of the procedure on the patient (for example, before anesthesia or before creating percutaneous access). Also, if using a remote control, a pump, a Carto® System, or an electrophysiology recording system, verify that the connections to those systems are functional prior to starting the first steps of the procedure. Doing this helps to detect problems with the device before the patient is in a phase of the intervention in which interruption could lead to an increased risk to the patient's health. Also perform a visual inspection of the accessories (see Section 5.3, Caring for Accessories).

8. Use only catheters that have been approved for use with the maximum voltage specified in this user manual (see Section 8.1, Specifications).

9. Use only accessories that have been provided by or recommended by the generator's manufacturer (see Chapter 5, Accessories). The use of other accessories can have a negative effect on the technical specifications. Do not modify accessories. Visually inspect all accessories on a regular basis. Make sure that the connected cables are not damaged. When using sterile accessories, be sure to maintain the sterility of those accessories.

10. Place the generator on a secure, non-slip surface such as the CARTO® System cart. If the generator is placed on a mounting plate, make sure it is securely fastened. Do not place the generator directly above another device and do not place any other device directly on the generator. Make sure that there is enough free space on all sides of the generator to allow the heat created by the generator to escape.

11. The entire surface of the indifferent electrode must be as close as possible to the operating field and must have fully reliable contact with the patient's body. The skin surface must be free of excessive oil and body hair. (See Section 3.3, Warnings and Precautions: During an Ablation Procedure.)

12. The generator is equipped with a contact quality monitoring feature for split indifferent electrodes. If the contact quality falls below a defined value, the generator displays an alert message. However, if two split indifferent electrodes are used at the same time and one loses contact quality but the other maintains contact quality, no alert is triggered. If a solid indifferent electrode detaches from the patient's skin, no alert is triggered. When using a solid indifferent electrode, the hospital staff is responsible for ensuring proper contact of the electrode with the patient's skin.

13. The patient must not be in contact with grounded metal components or with metal components that have a large grounded area (for example, the operating table supports). For this purpose, the use of sufficiently insulating antistatic covers on the operating table is recommended. Electrostatic discharge (ESD) can give rise to extremely high current densities at the catheter tip, which can injure the patient. Therefore, do not touch the pins in the plug at the end of the catheter or the pins in the plug at the end of the cable after the catheter has been placed in the patient's body.

14. Skin contact between parts of the patient's body (for example, between the arms and the body) should not occur. Such contact can be avoided by using dry gauze, for example.

15. If the generator and physiological monitoring devices are used on a patient at the same time, all monitoring electrodes without protective resistances or RF filters should be applied to the patient's body as far away as possible from the ablation electrodes. Needle electrodes are not recommended for monitoring purposes. In all cases, it is appropriate to use monitoring electrodes and other monitoring devices that limit the RF current.

16. Position the connection cables of the ablation electrodes in such a way that they do not touch either the patient or other cables. Keep active electrodes that are temporarily not in use at a safe distance from the patient.

17. Set the RF power at only moderate output to avoid charring and clotting at the catheter ablation electrode.

18. When the SMARTABLATE™ RF Generator is used with irrigated catheters, monitor the irrigation flow rate to avoid hazards caused by insufficient irrigation flow. The approximate flow rate can be estimated by observing the drip speed in the drip chamber. The hospital staff is responsible for determining and monitoring the flow rate to avoid insufficient flow of the irrigation solution. The hospital staff is responsible for monitoring the total amount of solution delivered to the patient to avoid an excessive loading of the irrigation solution in the patient. For recommended flow rates, refer to the catheter's instructions for use.

19. Avoid using flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen (O_2) if the procedure is being performed in the region of the thorax or head, unless the gases are being aspirated off or an anesthesia-safe device is being used. Before starting RF ablation, allow time for flammable substances that are used as cleaning agents, disinfectants, or solvents to evaporate. There is a risk associated with flammable liquids under the patient or in the patient's body cavities. Wipe away the liquid in these places away before the generator is turned on. Beware of flammable endogenous gases. Materials such as cotton and gauze, when saturated with oxygen, can be ignited by sparks that arise even during normal use of the generator. (The foot pedal is suitable for use in operating rooms.)

20. Be aware during ablation procedures that in patients with cardiac pacemakers or pacemaker leads, there is a risk of interference with the pacemaker function or damage to the pacemaker. In case of doubt, consult the manufacturer of the device.

21. The electromagnetic radiation emitted by the generator can interfere with the function of other electrical devices. Conversely, other electrical devices can influence the function of the generator if they are operated at the same time in the immediate vicinity of the generator.

22. The plugs on the catheter and the catheter connection cable must not be brought into contact with parts that have high voltage (such as mains outlets) or metallic objects. This can lead to the patient's death by electrocution.

23. To avoid damage to the connection cables, do not wrap the cables around the generator or other apparatus. Coiling the connection cables during normal operation of the generator creates inductive components, which can lead to measurement errors. The values indicated in error can lead to misinterpretations.

24. Special safety measures with regard to electromagnetic compatibility (EMC) must be taken with electrical medical devices. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with this user manual, may cause harmful interference to radio communications. Similarly, portable and mobile communication devices may cause harmful interference to the functioning of the generator.

25. If error messages repeatedly appear, stop using the generator and contact Customer Support.

26. To avoid damage to the generator and its accessories, use only appropriate cleaning agents (see Sections 4.6, Cleaning and Disinfecting the Generator, and 5.4, Cleaning, Disinfecting, and Sterilizing Accessories).

27. To avoid the risk of electric shock, connect the mains cable from the generator mains socket (see Item 6 in Section 4.3, Controls on the Back of the Generator) to a 3-prong outlet that meets the specifications in Section 8.1, Specifications.

28. The generator may be opened only by persons authorized by the manufacturer. When the generator is open, parts that have high voltage or are very hot are accessible and can cause injury. If the generator is opened by an unauthorized person, any claims on the warranty are void. No modification of the generator is permitted.

29. If fluid penetrates into the generator, stop using the generator and contact Customer Support.

30. In the unlikely event that there is a fatal system error (the system will stop and the **Alarm** indicator will flash red), immediately disconnect the mains cable from the generator.

31. Electrodes and probes for monitoring and stimulation devices can be electrical conductors of RF current. Reduce the risk of burns by placing the electrodes and probes as far away as possible from the site of ablation and from the indifferent electrode.

32. To avoid possible injury to patients and medical personnel, do not start RF power application before the catheter is positioned in the intended ablation area.

33. To minimize electrical noise on the ECG recordings, position catheter connection cables so that they do not touch either the patient or other cables. For an optimal ECG trace, keep unused active surface electrodes at a distance from the patient.

34. To prevent fluid from impairing system performance, ensure that sterile catheters and cable plugs are completely dry.

35. To prevent a system malfunction, inspect all reusable accessories regularly. Do not use damaged cables.

36. Ablation data stored electronically must not be used for diagnosis or therapy. The intended use is for archiving or research only.

3.2 Warnings: System Safety and Connections

The SmartAblate™ RF Generator can be connected directly or indirectly to many other devices and accessories. The generator and the connected group of devices and accessories are referred to in the following warnings as the "system."

1. The generator connections for the ECG signals and for the stimulator are galvanically connected with the ablation catheter. Only cables and plugs approved for a CF type of device (CF safety classification) may be used (see Section 5.2, Accessory Lists).

2. All devices with these cables and plugs must fulfill the requirements stated in MDD/MPG for class 1 devices. Fulfillment of the requirements stated in IEC/EN 60601-1-1 and MDD 93/42/EEC must be monitored and documented in a suitable way.

3. The person who connects the generator and accessories to each other or who uses the generator and accessories is responsible and liable for installation and operation that complies with IEC/EN 60601-1-1.

4. All system components must comply with all applicable requirements and standards and be labeled pursuant to these standards.

5. If there are any concerns regarding the use of a component, contact the distributor of the component to obtain further information.

6. If several devices are connected to the generator and to each other, they should be as safe, both individually and together, as specified in IEC/EN 60601-1 and its sub-standards and IEC/EN 60601-1-2. All devices and accessories, when located within the patient area, must comply with IEC/EN 60601-1 and its sub-standards.

Keep in mind that the ECG connection cable for the generator creates a direct electrical connection to the patient's heart. Incorrect use of this connection can endanger the patient's life. Make sure that the leakage current of the connected system (in any combination) never exceeds the maximum permissible value (patient leakage current ≤ 0.05 mA).

Take into account that the system's RF leakage current can be negatively influenced by other system components. The maximum allowable values are specified in IEC/EN 60601-2-2. Displacements of the ECG baseline surface signals is a sign of uncontrolled RF current leakage through the body surface ECG electrodes. Heating of these electrodes gives rise to a shift in direct current voltage which, in turn, leads to a displacement of the baseline. In this case, check the whole system combination to avoid uncontrolled current leakage. It may also be the case, however, that the electrocardiograph is unsuitable for this use or that the body surface ECG electrodes have too high a contact impedance. Make sure that the ECG device is appropriate for this application. Skin burns at the body surface ECG electrodes can be a sign of uncontrolled current leakage.

7. There are many electrocardiographs to which a stimulator can be directly connected. The stimulator must be galvanically isolated (or physically disconnected) before the RF current is turned on. The reason for this is the parallel connection between the output of the generator and the stimulator. If the connection is not isolated, the stimulator's patient interface and safety insulation may be damaged. The transfer of RF energy into the electrodes connected to the stimulator can also cause injury to the patient.

8. Only classified electrical medical devices may be connected to the generator. If a PC system does not fulfill the requirements of IEC/EN 60601-1 / UL 60601-1 and their sub-standards, the distance between the PC system and the patient must be at least 1.83 m (6 ft) and the PC system must fulfill the requirements of IEC 950 / UL 60950-1. All medical devices that are connected electrically to the generator must fulfill the requirements of IEC/EN 60601-1-1, the standard for medical systems.

3.3 Warnings and Precautions: During an Ablation Procedure

1. Blood vessel perforation is a risk inherent in the placement of an electrophysiology catheter. The catheter needs to be moved carefully to avoid damage or perforation of blood vessels.

2. When performing ablation of the posterior wall of the left atrium, beware of the risk of forming a lesion in the esophagus.

3. Avoid high ablation temperatures. High ablation temperatures can lead to clot formation, charring of the heart tissue or blood, and/or evaporation of interstitial intracellular fluid.

   Note: The temperature indicated on the generator is not the tissue temperature. The indicated temperature is the temperature of the catheter's ablation electrode, which does not necessarily represent the tissue temperature. This applies especially when catheters with saline-cooled ablation electrodes are used.

   When catheters with cooled ablation electrodes are used, the temperature measurement reflects the temperature of the cooled electrode, not the temperature of the tissue. The temperature of the tissue may be distinctly higher and the risk of pop (explosion of steam bubbles) may increase. Therefore, use only moderate RF power output. Follow the recommendations in the instructions for use provided with the therapeutic catheters that are used with the system.

4. Keep in mind when setting the temperature that only the temperature of the electrode and not the temperature of the heart tissue is measured. Because of the cooling effect of blood flow, the temperature of the heart tissue may be higher than the temperature measured at the ablation electrode.

5. Avoid sudden increases in impedance to minimize charring at the ablation electrode. Charring at the ablation electrode can result in reduced RF energy delivery and/or an embolism.

6. Make sure that the active RF electrode of the ablation catheter is not in contact with another catheter or with another metallic conductor, such as an implanted pacemaker lead. This could lead to uncontrolled conduction of the RF energy to other parts of the body, or to an uncontrolled increase in the effective size of the active RF electrode.

7. Do not set any extreme, unrealistic limit values. The limit values serve to trigger an alarm when a limit value is exceeded. If unrealistic values are set, important alarm functions will be triggered too late or not at all.

8. To minimize the risk to the patient, keep the ablation duration to one minute or less.

9. When using the usual operating settings, a low output RF power or a problem with the ablation device can be a sign that the indifferent electrode is not correctly positioned or has poor contact with its connection cable.

10. Continuously monitor the generator's impedance measurement during RF energy application. If a sudden increase in impedance is observed, stop the RF energy delivery. Remove the catheter from the patient's body and clean the ablation electrode of the catheter with a sterile cloth to remove any adherent materials.

11. If there is any doubt about an unintended increase in RF energy or the proper functioning of the touch screen, **Data Entry Knob** , foot pedal, or remote control during RF delivery, immediately stop the RF energy delivery by pressing the **Stop** button on the generator, releasing the foot pedal, or pressing the **Stand-by** button. If none of these measures stops the RF energy delivery, disconnect the mains cable from the generator.

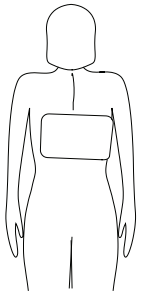
3.4 Handling Indifferent Electrodes

An indifferent electrode is used for unipolar ablations (see Section 1.4, Unipolar Application Method).

The indifferent electrode is monitored at all times by the generator.

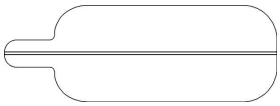
- To ensure patient protection, the generator prevents unipolar ablation in the absence of an indifferent electrode.
- If the indifferent electrode is not correctly connected to the generator, the generator immediately stops RF energy delivery and displays a message.
- The generator is equipped with a contact quality monitoring feature for split indifferent electrodes. When a split indifferent electrode is used, the generator displays an alert message as soon as skin contact with the electrode surface decreases by an unacceptable amount. After the indifferent electrode is applied to the patient, the generator continuously monitors the contact quality and updates an internal value for best achieved contact quality (the minimum

contact impedance of the split indifferent electrode). This value is reset every time the indifferent electrode is disconnected from the patient. The alert message appears when the contact impedance of the split indifferent electrode increases by 40% from the best achieved contact quality. If a solid (non-split) indifferent electrode is used and the electrode partially detaches itself, no alert is triggered. The danger of a skin burn under the indifferent electrode is thus increased.



Place the indifferent electrode within the operating field on the patient's back.

Solid indifferent electrode



Split indifferent electrode

The generator provides the option of connecting two separate indifferent electrodes. Both split and solid indifferent electrodes can be connected. In this case as well, the contact quality monitoring feature works only with split indifferent electrodes. However, if two split indifferent electrodes are used at the same time and one loses contact quality but the other maintains contact quality, no alert is triggered. The use of two indifferent electrodes doubles the size of the contact surface on the patient's skin. The use of two indifferent electrodes is recommended, especially for heavy patients with a low muscle mass, in ablations with high output (> 50 watts), and in the case of prolonged RF energy delivery (> 60 seconds). If two indifferent electrodes are used, apply one electrode to the left side of the ablation site and the other electrode to the right side of the ablation site, both at approximately the same distance from the ablation site. The two indifferent electrodes must not overlap.

Guide to the Use of Indifferent Electrodes with the SmartAblate™ RF Generator

- Use only indifferent electrodes with a surface area of ≥ 124 cm^2 that conform with either IEC/EN 60601-2-2 or ANSI / AAMI HF-18.
- Read the instructions for use for the indifferent electrodes carefully and take special note of the warnings and precautions sections.
- **For a single-use electrode:** Make sure that the electrode contact surface is not dry. If it is dry, replace it with a new, unused electrode before continuing with the ablation procedure. Do not use any contact gel with single-use electrodes. Use the single-use electrode for only one procedure. If the indifferent electrode becomes loose or needs to be moved, use a new indifferent electrode. Repeated use of an already applied electrode can mean a loss of adhesiveness and thus lead to distinctly poorer contact quality.
- **For a reusable electrode:** Make sure that the electrode contact surface is not dry. If it is dry, use a small, evenly distributed quantity of conductive gel.

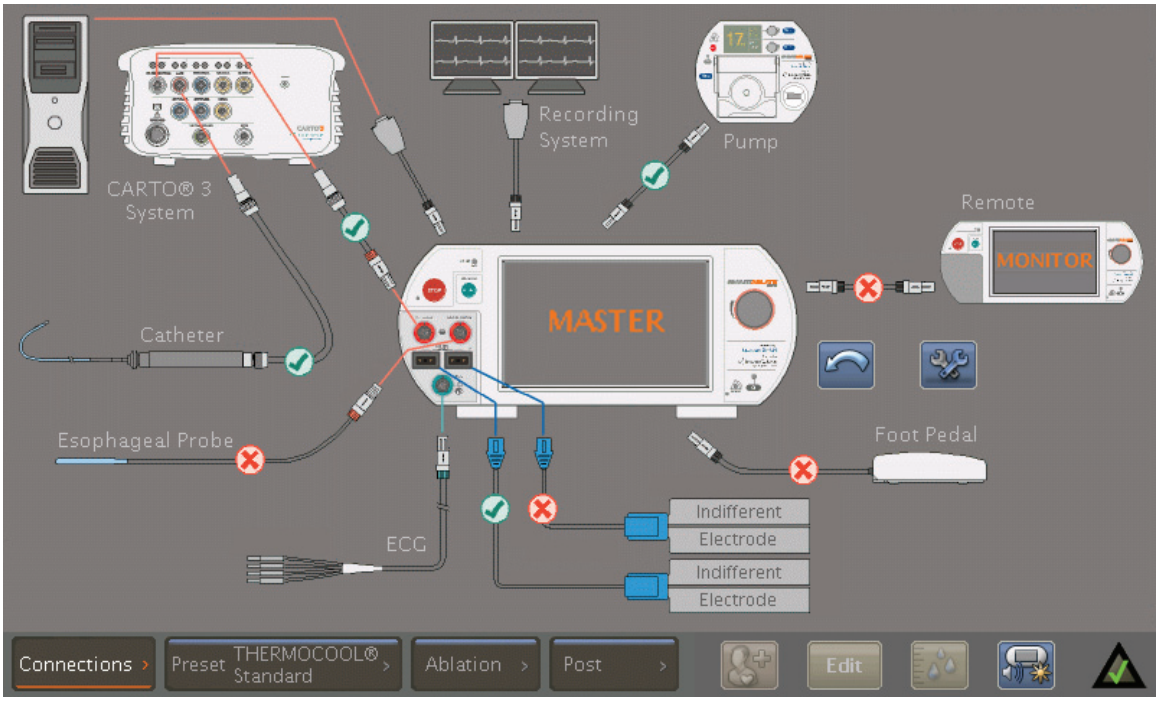
- **Carefully select the contact area:** Choose a muscular area on the back of the patient that is as near the heart as possible and that has sufficient blood flow. Do not place the indifferent electrode near wounds.
- **Carefully prepare the contact area:** Prepare the contact area on the patient and on the indifferent electrode according to the instructions for use provided with the indifferent electrode. Place the indifferent electrode closer to the ablation site than any ECG electrode or other products that could represent an alternative lead. Shave and degrease the skin.
- **Carefully apply the indifferent electrode to the contact area:** Make sure that the whole surface of the indifferent electrode forms a closed contact with the patient's back. There should be no pockets of air between the skin and the indifferent electrode. Oil, hair, dirt, repeatedly used adhesive electrodes, and electrodes of low quality can impair contact quality and increase the risk of a skin burn.
- Heat produced by thermal blankets or other sources of heat adds to the heat arising under the indifferent electrode. This increases the risk of skin burns. Do not use such sources of heat in immediate proximity to the indifferent electrode.

WARNING
An unsuitable indifferent electrode or an incorrectly applied indifferent electrode can lead to burns on the skin surface. Check the indifferent electrode and the connection cable before use. Do not use these if they are damaged or modified.

4 System Overview and Setup

4.1 Structure and Features

The SmartAblate™ RF Generator is a radiofrequency generator designed for use in cardiac ablation procedures. The generator can be configured to work with a variety of other devices and meets the highest standards for safety, precision, and ease of operation.



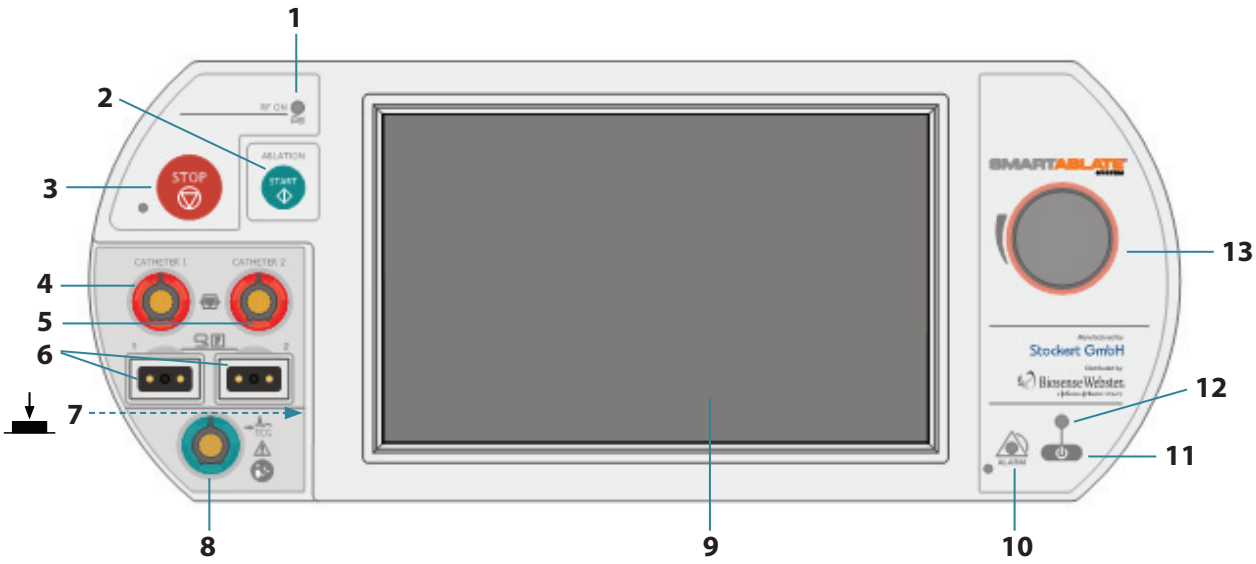
(The Esophageal Probe shown above is not applicable for the US and JP versions of the generator.)

The generator is compatible with a large number of catheters and devices. For a listing of devices and accessories, see Section 5.2, Accessory Lists.

The generator is operated via an easy-to-use user interface. Selections can be made on the screen by touching it (even when wearing surgical gloves) or by tapping it with a pen.

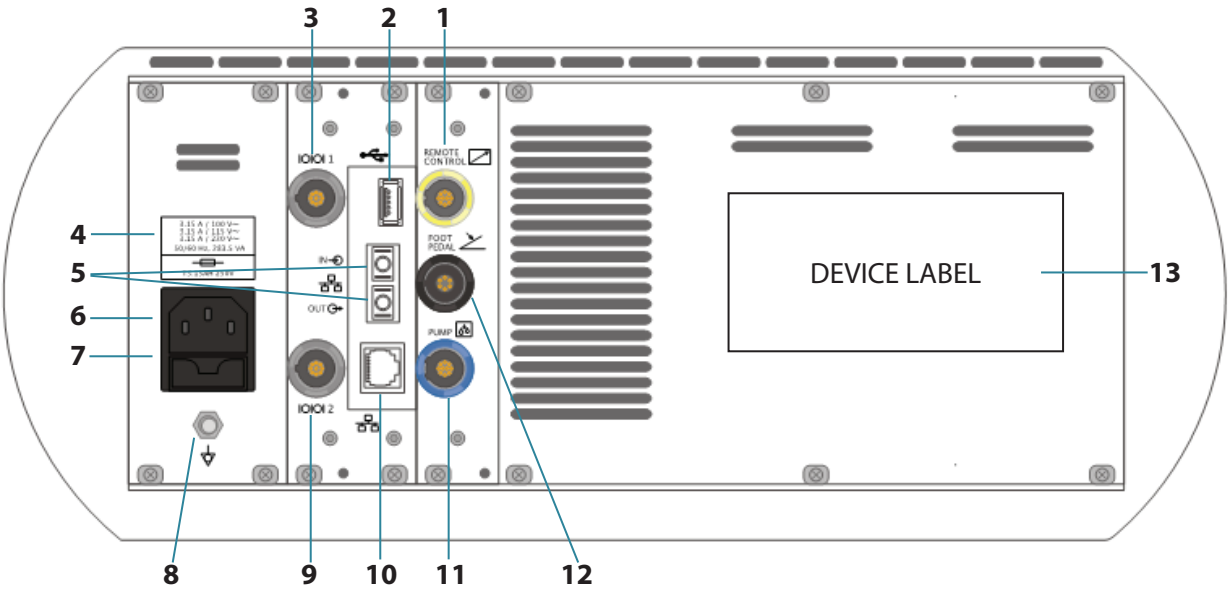
The generator features redundant protection circuits (if one safety mechanism fails, a second safety mechanism indicates the failure to ensure safety). A central computer processor operates the device. Several other microprocessors control the various functions, such as RF power output and calculation of impedance. The generator is equipped with a memory unit that stores the settings even after the generator has been turned off. These settings are active when the generator is turned on again. Operating errors and defects in the attached devices are detected and error messages are issued. For a list of possible error messages, see Sections 7.2, Warnings, Alerts, and Ablation Stop Reasons and 7.3, System Errors.

4.2 Controls on the Front of the Generator



Item	Description
1	**RF On** indicator
2	**Ablation Start** button
3	**Stop** button
4	**Catheter 1** – receptacle for ablation catheter cable
5	**Catheter 2** – receptacle for esophageal probe cable *(not functional in the US and JP versions of the generator)*
6	Receptacles for indifferent electrode cables
7	**Tilt Panel** button (on side of front panel) *(not available on some models)*
8	Receptacle for ECG cable (external stimulator /electrophysiology recording system)
9	Touch screen
10	**Alarm** indicator
11	**Stand-by** button
12	**Stand-by** indicator
13	**Data Entry Knob**

4.3 Controls on the Back of the Generator



Item	Description
1	**Remote Control** – Receptacle for SmartAblate™ Remote Control cable
2	USB port
3	Serial data port 1 – for electrophysiology recording system
4	Mains rating label
5	Fiber optic ports *(not implemented)*
6	Mains socket
7	Fuse cover
8	Potential equalization port
9	Serial data port 2 – for Carto® System
10	Ethernet port *(not implemented)*
11	**Pump** – Receptacle for SmartAblate™ Irrigation Pump cable
12	**Foot Pedal** – Receptacle for SmartAblate™ System foot pedal cable
13	Device label

4.4 Functional Test and On-Site Training

The SmartAblate™ RF Generator is a medical device. In some countries, in order to comply with local regulations, the generator may not be put into service until the distributor has subjected the generator to a functional test on site and has trained the person responsible for operating the device in the handling of the generator per this user manual. All applicable requirements of local regulations must be followed.

A functional test of the generator can be performed using a STOCKERT test box for the SmartAblate™ RF Generator, which is available for purchase (see Section 5.2, Accessory Lists). See the instructions for use that are provided with the test box.

4.5 Setup

4.5.1 Setting Up the Generator

The SmartAblate™ RF Generator may be used only in medical rooms in compliance with IEC/EN, Annex A.4, Clause 16.

Place the generator on a secure, non-slip surface such as the Carto® System cart. If the generator is placed on any other surface, make sure it is securely fastened.

Do not place the generator directly above another device and do not place any other device directly on the generator.

Make sure that there is enough free space on all sides of the generator to allow the heat created by the generator to escape.

4.5.2 Mains Connection

The SmartAblate™ RF Generator automatically adjusts for the necessary mains voltage and frequency. To avoid the risk of electric shock, connect the mains cable from the generator mains socket (see Item 6 in Section 4.3, Controls on the Back of the Generator) to a 3-prong outlet that meets the specifications in Section 8.1, Specifications. Use only the mains cable supplied by the manufacturer or distributor for the country where the generator is being used.

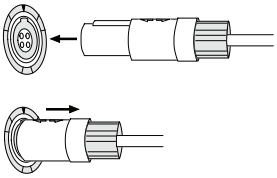
4.5.3 Fuses

Externally accessible fuses for the SmartAblate™ RF Generator are located under the fuse cover (see Item 7 in Section 4.3, Controls on the Back of the Generator). Use only fuses approved by the manufacturer.

4.5.4 Potential Equalization

To avoid differences in potential between the generator and other devices with power operation, the SmartAblate™ RF Generator must be connected to a grounding line (as specified in IEC/EN 60601-1). Connect one end of the green and yellow potential equalization cable provided with the generator to the grounding connection on the back of the generator (see Item 8 in Section 4.3, Controls on the Back of the Generator). Connect the other end to the room's central grounding line. To avoid radiation interference (noise) in the ECG signal, always use the same grounding line for connection of all devices involved (electrocardiograph, Carto® System, generator).

4.5.5 Circular Plug Connections



The circular plugs on the accessory cables are the same color as the receptacles on the front and back of the generator (see Sections 4.2, Controls on the Front of the Generator, and 4.3, Controls on the Back of the Generator). To connect an accessory cable to the generator, align the arrow on the plug with the mark on the receptacle and push in without unnecessary force until a click indicates that the connector is locked in the receptacle. If the plug does not fit in the receptacle, verify that the color coding matches and that the number of pins in the plug is appropriate for the receptacle. To remove the plug, gently pull back the sleeve on the plug and pull the plug out of the receptacle.

4.5.6 Connection Cables and Catheters

Use only ablation catheters with temperature sensors and connection cables supplied by or recommended by the manufacturer. Other catheters may be used only after consultation with the distributor. For recommended accessories, see Section 5.2, Accessory Lists.

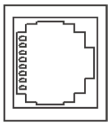
To connect an ablation catheter, use a sterile cable and connect one end to the **Catheter 1** receptacle on the front of the generator (see Item 4 in Section 4.2, Controls on the Front of the Generator) and the other end to the catheter. Alternatively, if the ablation catheter is connected to an additional system, such as the Carto® System, connect the cable from the system to the **Catheter 1** receptacle.

To connect an esophageal probe, connect the appropriate cable to the **Catheter 2** receptacle on the front of the generator (see Item 5 in Section 4.2, Controls on the Front of the Generator). *(An esophageal probe cannot be used with the US or JP versions of the generator. The **Catheter 2** receptacle is not functional.)*

4.5.7 Indifferent Electrode Connections

The receptacles on the front of the generator for the indifferent electrodes (see Item 6 in Section 4.2, Controls on the Front of the Generator) can be used to connect both solid and split indifferent electrodes. Some of the indifferent electrodes recommended for use with the SmartAblate™ RF Generator are available with cables that have the appropriate mating component. For other indifferent electrodes, appropriate adapter cables are available.

4.5.8 Ethernet Connection



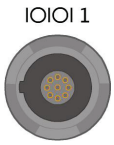
The Ethernet port on the back of the generator (see Item 10 in Section 4.3, Controls on the Back of the Generator) is provided for future use.

4.5.9 USB Connection

Only USB mass storage devices (such as USB flash drives) may be connected to the USB port on the back of the generator (see Item 2 in Section 4.3, Controls on the Back of the Generator). Do not connect any other USB devices (such as a printer, mouse, or scanner); these other devices are not supported by the generator.

Note: The USB ports on the back of the tilting front panel of the generator are for use by service technicians only.

4.5.10 Serial Data Connections



Devices that exchange data with the generator, such as the CARTO® 3 System, the CARTO® XP System, compatible electrophysiology recording systems, and other external compatible monitoring systems can be connected to the serial data ports on the back of the generator (see Items 3 and 9 in Section 4.3, Controls on the Back of the Generator).

4.5.11 Fiber Optic Connections

The fiber optic ports on the back of the generator (see Item 5 in Section 4.3, Controls on the Back of the Generator) are provided for future use.

4.5.12 Setting Up Irrigated Catheters with the Irrigation Pump and Tubing

Connect the SMARTABLATE™ RF Generator to the SMARTABLATE™ Irrigation Pump by plugging one end of the connection cable into the **Pump** receptacle on the back of the generator (see Item 11 in Section 4.3, Controls on the Back of the Generator) and the other end of the cable into the appropriate receptacle on the back of the pump.

Connect a SMARTABLATE™ Irrigation Tubing Set with the pump and with an irrigated catheter as described in the SMARTABLATE™ Irrigation Pump user manual. Also see Section 6.6, Flushing to Eliminate Air in the Tubing and Catheter.

4.5.13 Tilting the Generator's Front Panel (Generators with a Tilt Panel button)

After the generator has been turned on (see Section 6.1.1, System Startup), the front panel can be tilted for easier viewing. Press the **Tilt Panel** button (see Item 7 in Section 4.2, Controls on the Front of the Generator) to release the lock and gently pull the bottom of the front panel forward.

Note: The generator's front panel cannot be adjusted when the generator is off. Before moving the generator, make sure that the front panel is closed.

4.5.14 Tilting the Generator's Front Panel (Generators without a Tilt Panel button)

The front panel can be tilted for easier viewing (the generator does not have to be turned on). Gently pull the bottom of the front panel forward until it is at the desired angle, then release it. The front panel will lock into place. To lower the front panel, gently pull the front panel forward slightly and then let it glide backward.

4.6 Cleaning and Disinfecting the Generator

WARNINGS

- The SmartAblate™ RF Generator must be turned off and the mains cable must be disconnected from the generator before cleaning and disinfecting the generator.
- The SmartAblate™ RF Generator, mains cable, grounding cable, serial connection cable, and the indifferent electrode cable must not be sterilized. Note: Some accessories may need sterilization; follow the instructions for use that are provided with the accessories.

Use a dry microfiber cloth to clean the generator's touch screen. If damp cleaning is necessary, moisten a soft cotton or linen cloth with commercial glass cleaner that does not contain alcohol and wipe the screen. Do not spray the cleaner directly onto the screen.

Use a soft, damp, lint-free cloth to clean and disinfect the housing of the generator. Use only non-flammable and non-explosive substances. Water or soapy water is recommended for cleaning. Make sure that no liquid penetrates the inside of the generator.

The following disinfectants may be used for disinfecting the generator and its cables:

- Lysoformin® spezial
- Kodan®
- Meliseptol®
- Commercial disinfectants that do not contain ethyl alcohol

Caution: The following substances must not be used: acetone, benzene, acids of any kind (including acetic acid and citric acid), scouring agents, nitro dilutions and other organic solvents. Do not use any agent containing ethyl alcohol to clean the generator. Iodine or disinfectants containing dyes cause discoloration of the housing and should not be used. Perform disinfection by wiping, not by spraying. Avoid condensation. If cleaning or disinfecting the generator with flammable or explosive substances cannot be avoided, make sure these substances have completely evaporated before the generator is turned on.

Check the vents on the bottom and sides of the generator regularly for excessive deposits of dust and foreign bodies. Carefully brush or wipe off the unwanted material.

4.7 Protecting Against Damage

In addition to being operated and maintained per the instructions in this user manual, the SmartAblate™ RF Generator must also be protected against damage. This includes installing the generator in a safe location and protecting the generator against moisture, contamination, and contact with flammable or explosive substances.

Make sure that all cables to devices and accessories are arranged in a way that prevents tripping.

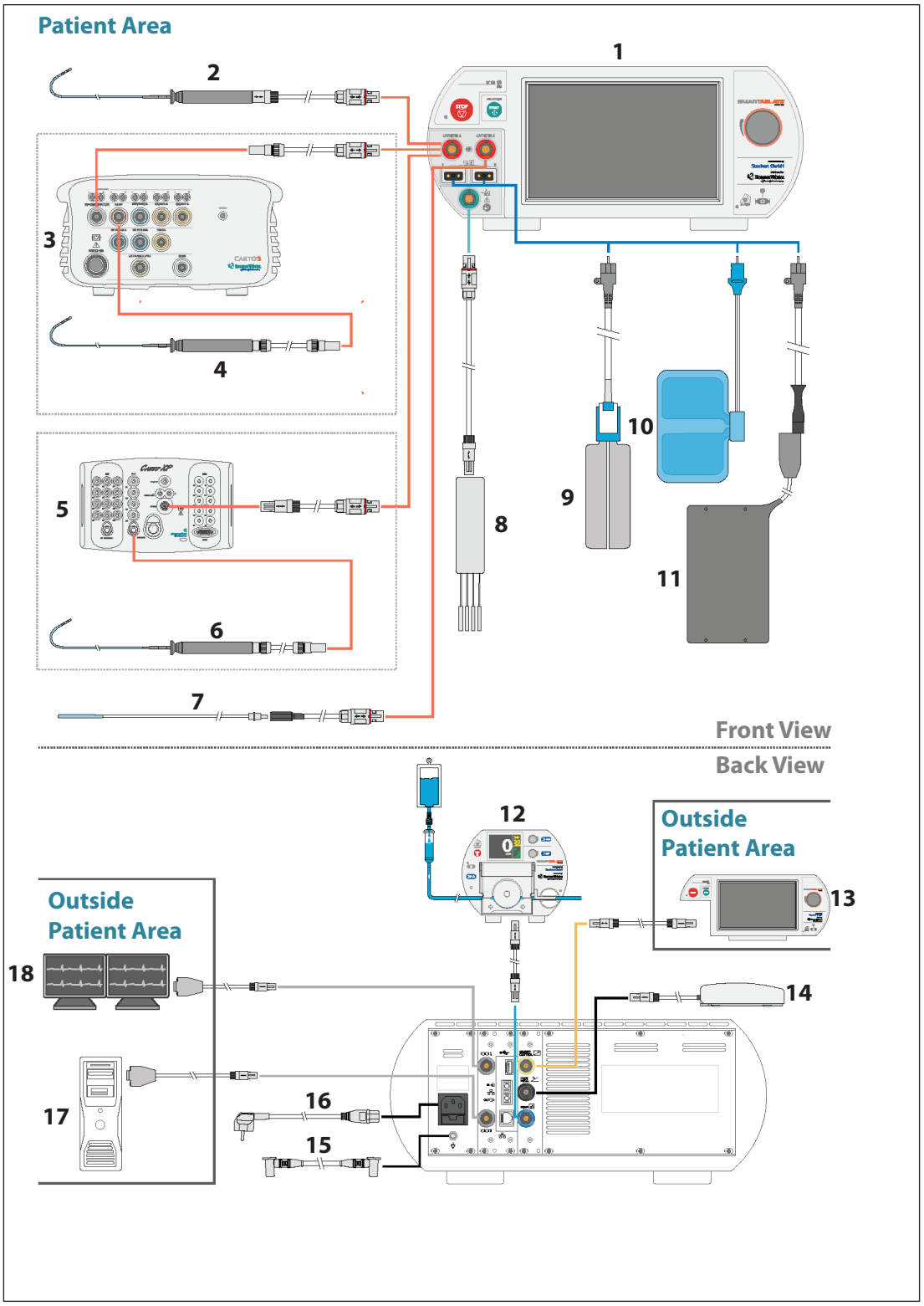
Make sure that the front panel of the generator is closed before moving the generator. Hold the sides of the generator, not the front panel, when lifting the generator. Carry the generator with two hands. To transport the generator over long distances or to send the generator for service, use the original packaging. If the original packaging is not available, contact the manufacturer or distributor for a replacement.

4.8 Disposal

Inadequately treated electrical and electronic waste poses environmental and health risks. Follow local regulations for disposal of the SmartAblate™ RF Generator and its electrical or electronic accessories. To ensure proper disposal, there is also the option of contacting your Biosense Webster representative regarding return of the generator and its accessories.

5 Accessories

5.1 Diagram of the Generator and Accessories



Item	Description
1	SmartAblate™ RF Generator
2	Catheter
3	Carto® 3 System
4	Catheter
5	Carto® XP System
6	Catheter
7	Esophageal probe *(not applicable for the US and JP versions of the generator)*
8	ECG connection
9	Split indifferent electrode
10	Split indifferent electrode
11	Erbe indifferent electrode
12	SmartAblate™ Irrigation Pump
13	SmartAblate™ Remote Control
14	Foot pedal
15	Grounding cable
16	Mains cable
17	Personal computer or Carto® System
18	Electrophysiology recording system

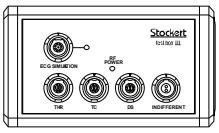
5.2 Accessory Lists

The following is a list of accessories for the SmartAblate™ RF Generator.

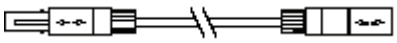
WARNING
Use only the original accessories provided by or recommended by the manufacturer of the SmartAblate™ RF Generator. If you use accessories that are not authorized by the manufacturer, the safety of the device and system is not guaranteed.

5.2.1 Devices

Item	Part #	
SmartAblate™ Irrigation Pump		
Worldwide, except USA, Japan, China	M4900103	
USA	M490003	
Japan	M4900203	
China	M4900403	

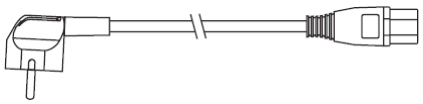
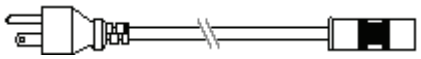
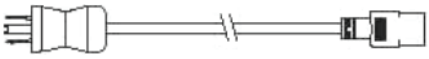
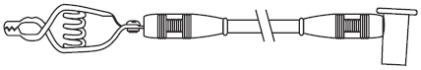
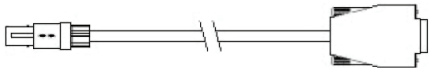
Item	Part #	
SmartAblate™ Remote Control		
Worldwide, except USA, Japan, China	M4900104	
USA	M490004	
Japan	M4900204	
China	M4900404	
STOCKERT Testbox III	39F45X	

5.2.2 Foot Pedal

Item	Part #	
Foot Pedal, length of connection cable: 3 m		
Worldwide, except China	M490005	
China	M4900405	
Foot Pedal Extension Cable, length: 7 m (Redel-6 → Redel-6, black)	M490026	

5.2.3 SmartAblate™ Cables

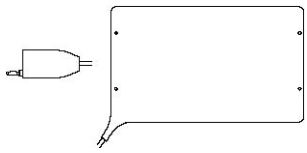
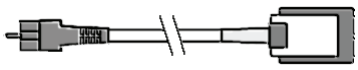
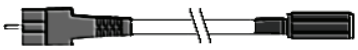
Item	Part #	
Connection Cable from SmartAblate™ RF Generator to SmartAblate™ Remote Control (Redel-10 → Redel-10, yellow)		
length: 10 m	M490010	
length: 15 m	M490029	
length: 25 m	M490012	
length: 30 m	M490013	
Connection Cable from SmartAblate™ RF Generator to SmartAblate™ Irrigation Pump (Redel-10 → Redel-10, blue)		
length: 1 m	M490027	
length: 3 m	M490016	
length: 5 m	M490028	
length: 10 m	M490030	

Item	Part #	
Mains Cable, length: 3 m		
Australia	M4900601	
Brazil	M4900609	
China	M4900410	
EU	M4900108	
India / South Africa	M4900604	
Israel	M4900606	
Japan	M4900210	
Russia	M4900603	
Switzerland	M4900605	
Taiwan	M4900607	
UK / Singapore / Hong Kong	M4900602	
USA	M490024	
Grounding Cable, length: 3 m		
Worldwide, except Japan	M490014	
Japan	M490015	
ECG Connection Cable, length: 3 m (Redel-16 → 4 x 2 mm tip pins, green)	M490018	
Serial Data Communication Cable for CARTO® Systems or Electrophysiology Recording Systems (Redel-9 → Dsub-9, gray)		
length: 3 m	M490021	
length: 5 m	M490025	
length: 15 m	M490023	
Connection Cable for Smiths Esophageal Probe, Rectangular 2 pin, length: 3 m *(not applicable for the US and JP versions of the generator)*	M490019	—
Connection Cable for Philips Esophageal Probe, accepts mini (1/8") phone plug, length: 3 m *(not applicable for the US and JP versions of the generator)*	M490020	
Connection Cable from STOCKERT Testbox III to an indifferent electrode	M490017	

Item	Part #	
Connection Cable for CELSIUS® Catheters (TC/THR, Redel 26 → Redel 10, red), length: 3 m	D130302	
Connection Cable for CELSIUS® Catheters (DS, Redel 26 → Redel 10, green), length: 3 m	D130303	
Connection Cables from SmartAblate™ RF Generator to ablation catheters (available in Europe), length: 3 m		
APTMedical Triguy-D	M4900622	
Boston Scientific / EPT	M4900610	
Osypka	M4900611	
Osypka Easy-TC	M4900620	
Osypka Plus Flutter	M4900619	
Bard	M4900612	
St Jude Medical / IBI	M4900613	
St Jude Medical / DAIG	M4900614	
Biotronik	M4900615	
Medtronic	M4900616	

5.2.4 Indifferent Electrodes and Cables available from STOCKERT GmbH

Other indifferent electrodes that meet the requirements specified in Section 3.4, Handling Indifferent Electrodes, are also compatible with the SmartAblate™ RF Generator.

Item	Part #	
Erbe Indifferent Electrode for Children, reusable, 17 x 11 cm	39D-15X	
Erbe Indifferent Electrode for Adults, reusable, 17.5 x 29.5 cm	39D-19X	
Connection Cable for 3M Indifferent Electrode with Clip, length: 3 m	M490035	
Connection Cable for Erbe Indifferent Electrode with 4-mm Phone Jack, length: 3 m	M490034	

5.2.5 Catheters

For recommended catheters, contact Customer Support.

Note: The UL mark on this generator is only valid with accessories tested by Underwriters Laboratories. See http://www.stockert.de/fileadmin/downloads/Tested_accessories_by_UL.pdf.

5.3 Caring for Accessories

WARNING
Do not modify any accessories.

5.3.1 Connection Cables

Visually inspect all connection cables before each use. Do not use damaged cables.

To avoid damage to the connection cables, do not wrap the cables around the generator or other apparatus. Coiling the connection cables during normal operation of the generator creates inductive components which can lead to measurement errors. The values indicated in error can lead to misinterpretations.

When plugging in a cable or unplugging a cable, hold the cable by the plug housing, not by the cable itself.

5.3.2 Indifferent Electrodes

Follow the instructions in Section 3.4, Handling Indifferent Electrodes, and the instructions for use that are provided with the indifferent electrodes.

5.3.3 Foot Pedal

Never pick up the foot pedal by its cable. Do not coil the cable closely around the foot pedal. Check the cable regularly for visible damage. Do not use a damaged foot pedal.

5.4 Cleaning, Disinfecting, and Sterilizing Accessories

To ensure that the accessories are safe to use, follow the cleaning, disinfecting, and sterilizing instructions in the instructions for use provided with the accessories. Make sure that any liquid is removed from electrical contacts after cleaning, disinfecting, or sterilizing.

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6 Generator Operation

6.1 Quick Overview

6.1.1 System Startup

Quick Steps

- Connect the generator to the mains supply.
- Press **Stand-by** to turn on the generator.
- At the message, press **Stop**.
- Optionally, turn on the remote control.
- For irrigated catheters, set up and turn on the pump.

Notes

1. When you press **Stand-by**, make sure that **Ablation Start** and **Stop** and the foot pedal are not pressed.
2. When you turn on the generator, the generator's audible and visual indicators are tested to allow you to verify that they are functional. The **Stand-by** indicator lights up and the SmartAblate™ System logo appears on the screen. The **Alarm** indicator flashes alternately red and orange for a short time to indicate that the **Alarm** indicator is working. Also, the **RF On** indicator flashes orange and an audible RF tone is played briefly. If the indicators listed above do not perform as described, there is a problem with the generator and you should contact Customer Support.
3. Progress dots in the bottom left corner of the screen indicate that the system is performing a self test. When the self test is successfully completed, a confirmation message appears asking you to press **Stop** to continue. After you press **Stop**, the **ABLATION** screen will appear. If the progress dots do not appear, or if the number of dots stops increasing and the logo remains on the screen, or if the confirmation message does not appear, there could be a problem (see Section 7.4, Other Troubleshooting).
4. Always wait until the automatic self test has been successfully completed before starting the first steps of the procedure on the patient (for example, before anesthesia or before creating percutaneous access). Also, if using a remote control, a pump, a Carto® System, or an electrophysiology recording system, verify that the connections to those systems are functional prior to starting the first steps of the procedure. Doing this helps to detect problems with the device before the patient is in a phase of the intervention in which interruption could lead to an increased risk to the patient's health. Also perform a visual inspection of the accessories (see Section 5.3, Caring for Accessories).

6.1.2 System Shutdown

Quick Steps

- Stop ablation (see Section 6.4.2, Starting and Stopping Ablation).
- Press and hold **Stand-by** for approximately 3 seconds to turn off the generator.
- Turn off the remote control.
- For irrigated catheters, turn off the pump.

Note You can turn off the pump and remote control before or after you turn off the generator.

6.1.3 Screens

The SmartAblate™ RF Generator has four primary screens, represented by the first four buttons on the Navigation Bar. See Section 6.9, Flowchart of the Screens, for a chart that lists other screens that can be accessed from these primary screens.

Table 1 – Screens

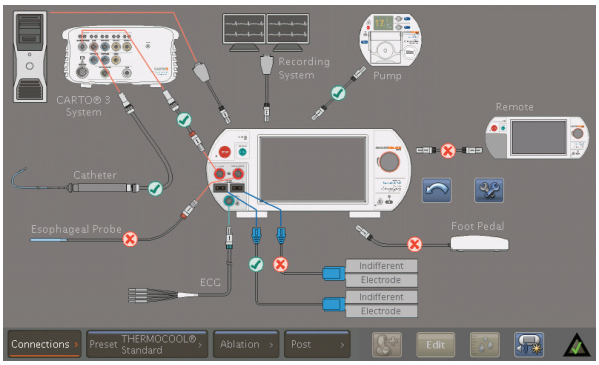
Screen	Description	Section
CONNECTIONS	 *(The Esophageal Probe shown above is not applicable for the US and JP version of the generator.)* • Shows all devices that you can connect to the SmartAblate™ RF Generator. • Indicates which devices are currently connected and functioning properly. • Provides access to information about the connected devices. • Provides access to the System Settings screen.	6.2, Connections

Table 1 – Screens

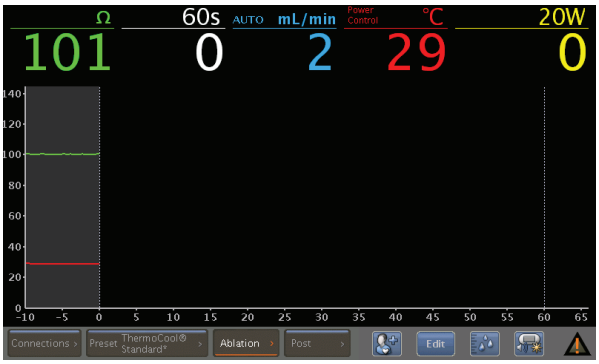
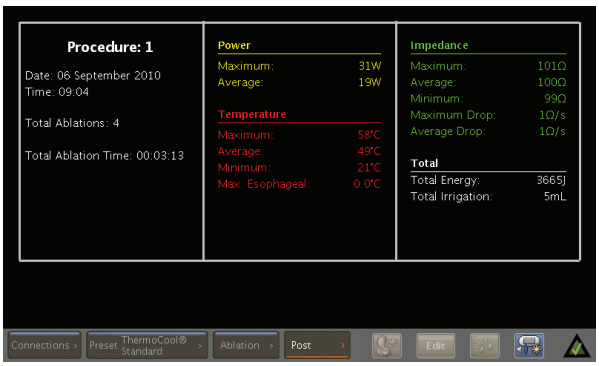
Screen	Description	Section
PRESET	 ▪ Provides access to selecting, editing, creating, and deleting presets. ▪ Provides access to the Irrigation Control screen, the Audio Settings screen, and the Display Settings screen.	6.3, Presets
ABLATION	 ▪ When the **ABLATION** screen is displayed, you can press **Ablation Start** and **Stop** or the foot pedal to start or stop ablation. ▪ The screen displays ablation measurement information and provides the ability to change common settings while viewing the **ABLATION** screen. ▪ When the Navigation Bar is displayed with the **ABLATION** screen (before or after ablation), you can press **Edit** on the Navigation Bar to change additional settings. You can press **Irrigation Control** to modify irrigation settings for an irrigated catheter. You can press **System Control** to change the volume or the brightness of the screen and to indicate whether the generator or remote control has control of the system. ▪ When ablation stops, the Ablation Summary appears.	6.4, Ablation

Table 1 – Screens

Screen	Description	Section
POST	 *(The Max. Esophageal temperature shown above is not applicable for the US and JP versions of the generator.)* • Displays the **POST** (Post Procedure) screen.	6.5, Post Procedure

6.1.4 Screen Features

Sample Screen (PRESET Screen)

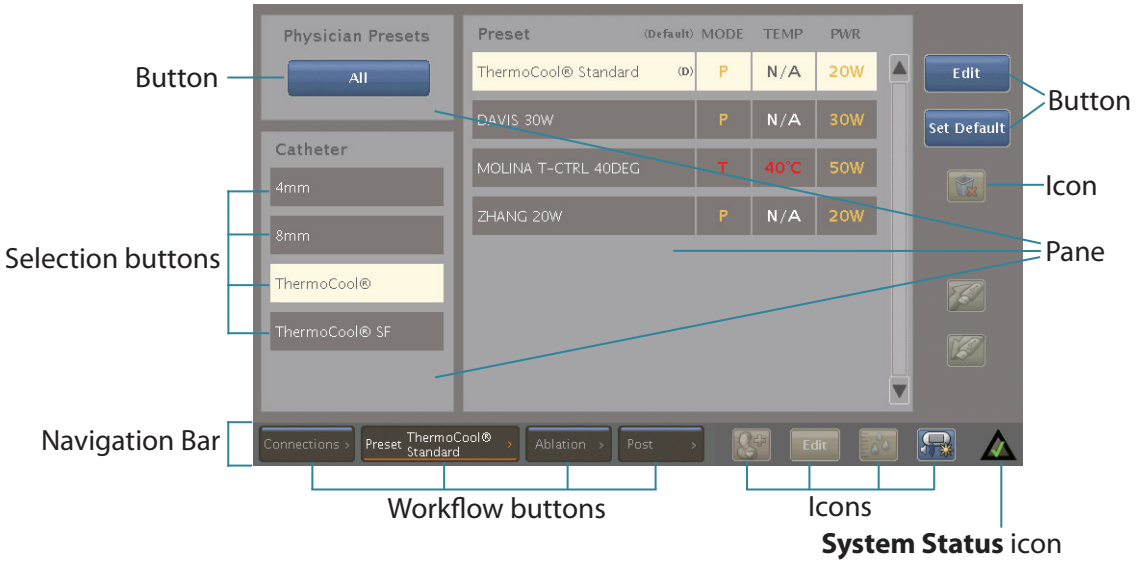


Table 2 – Screen Features

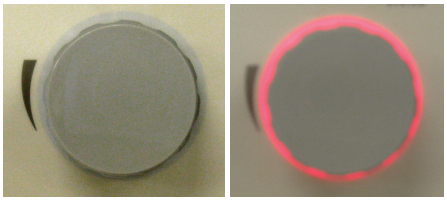
Name	Description	How to Use
Button	Blue, raised	Press the button to display another screen or perform an action.
Selection button	Gray, flat (white when selected)	Press one button to make a selection from a group of buttons.

Table 2 – Screen Features

Name	Description	How to Use
Workflow button	Black, flat (on Navigation Bar)	Press the button to display the screen named on the button. The workflow button for the displayed screen has an orange underscore.
Icon	Image	Press the icon to perform the action represented by the image on the icon (see Section 6.10, Icons on the Screens).
System Status icon	Image, triangle	See Sections 7.2, Warnings, Alerts, and Ablation Stop Reasons, and 7.3, System Errors.
Pane	Rectangular gray section of the screen	Provides visual grouping of related buttons and information.

Note: When raised buttons are gray and when icons are gray, either they are not available for use on the screen that is displayed or their functions are not supported by the software version.

6.1.5 Data Entry Knob



The **Data Entry Knob** is used to change values on the generator screens. When you press a displayed value on the touch screen, the ring around the **Data Entry Knob** turns on. The color of the ring matches the color of the value or the color of the background surrounding the value.

When you turn the **Data Entry Knob**, the value changes. Press the knob to save the new value. The ring around the knob will turn off. You can also save the new value by pressing a different displayed value or by waiting until the ring around the knob turns off by itself.

Note: At the **ABLATION** screen, the changed values take effect immediately (it is not necessary to press the knob).

6.1.6 Foot Pedal

If a SmartAblate™ System foot pedal is connected to the generator, the foot pedal can be used to start and stop ablation (see Section 6.4.2, Starting and Stopping Ablation).

Note: If a SmartAblate™ Irrigation Pump is connected to the generator and a SmartAblate™ System foot pedal is connected to the pump, that foot pedal controls only the pump.

6.1.7 Typical Procedure Process – Quick

Quick Steps

- Physically connect devices to the generator.
- Turn on the generator.
- Press the **PRESET** workflow button.
- Select a preset.
- Press the **ABLATION** workflow button.
- Press **Ablation Start** to start ablation.

Note

At a minimum, connect a catheter and an indifferent electrode to the generator. For an irrigated catheter, also connect a pump with a flushed tubing set (see the instructions for use for the SmartAblate™ Irrigation Pump, the instructions for use for the SmartAblate™ Irrigation Tubing Set, and Section 6.6, Flushing to Eliminate Air in the Tubing and Catheter.)

6.1.8 Typical Procedure Process – Full

Quick Steps

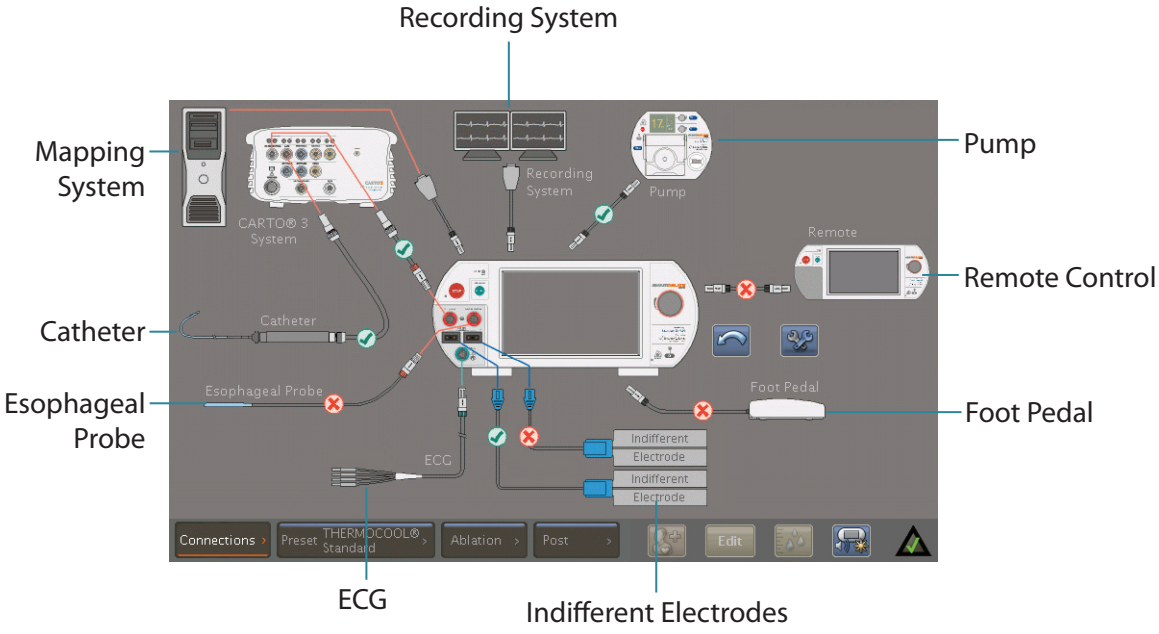
• Turn on the generator and remote control.	(6.1.1, System Startup)
• At the **CONNECTIONS** screen, review the device connections.	(6.2, Connections)
• Physically connect all applicable devices to the generator.	
• Physically connect all applicable devices to the patient.	
• At the **PRESET** screen, select or create a preset.	(6.3, Presets)
• Go to the **ABLATION** screen, then position the catheter at the first ablation site.	
• Press **Ablation Start** or press and hold the foot pedal to start ablation.	(6.4, Ablation)

Notes

1. At a minimum, connect a catheter and an indifferent electrode to the generator. For an irrigated catheter, also connect a pump and a flushed tubing set (see the instructions for use for the SmartAblate™ Irrigation Pump, the instructions for use for the SmartAblate™ Irrigation Tubing Set, and Section 6.6, Flushing to Eliminate Air in the Tubing and Catheter).
2. Optionally, connect other devices shown on the **CONNECTIONS** screen.
3. You can also start ablation by pressing **Ablation Start** on the front of the remote control or by pressing the foot pedal connected to the remote control when the remote control is the system Master (see Section 6.7, System Control).

6.2 Connections

CONNECTIONS Screen (Displaying CARTO® 3 System)



(The Esophageal Probe shown above is not applicable for the US and JP versions of the generator.)

Quick Steps

- Press the **CONNECTIONS** workflow button.
- Press the image for any device (except the ECG cable) to view information about the device and/or to test the interface between the generator and the device (see Table 3 – Device Screens in this section).
- Press **Front/Back** to view the connections on the back of the generator.
- Press **System Settings** to open the System Settings screen (see Table 4 – System Settings Screen Options in this section).

Note

See Section 7.1, Device Connections, for an explanation of the meaning of and for each device connection.

Sample Device Screen

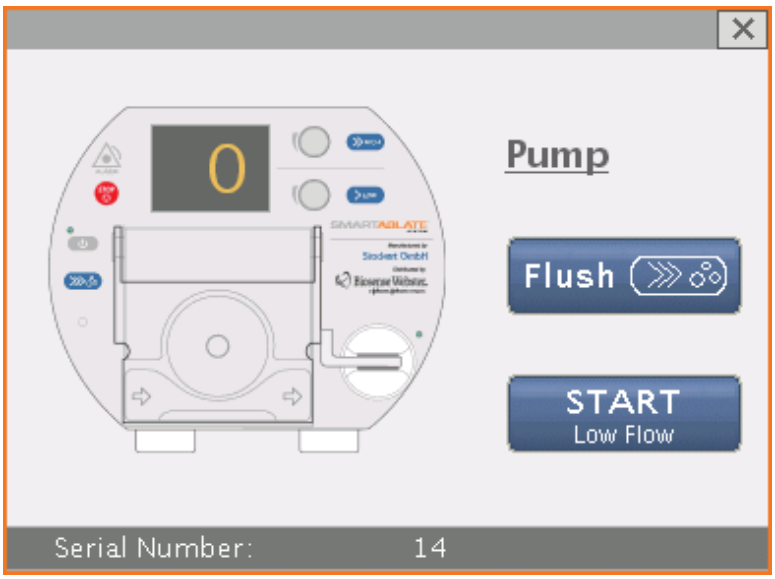


Table 3 – Device Screens

Device	Information Displayed	Action	Action Description
Generator	· Device name · Manufacturer · Serial number · Software and hardware versions · Last and next preventive maintenance dates · Customer name and number	N/A	N/A
Mapping System (CARTO® 3 System, CARTO® XP System, or Other)	· Image of generator and mapping system	**Change**	Press **Change**, then press the image of the connected mapping system. The mapping system image on the **CONNECTIONS** screen will change when this screen closes.

Table 3 – Device Screens

Device	Information Displayed	Action	Action Description
	• After selecting the mapping system, images and values appear for verifying transmission of impedance data	**TRANSMIT**	Press **TRANSMIT** to test the communication on the mapping system connection port (see Item 9 in Section 4.3, Controls on the Back of the Generator). The color in the arrow moves from left to right to indicate that the test is running. The number on the screen is the impedance value being sent to the mapping system.
		STOP	Press **STOP** to stop the transmission test.
Recording System	• Image of generator and recording system • Values for verifying transmission of data	**TRANSMIT**	Press **TRANSMIT** to test communication through the recording system port (see Item 3 in Section 4.3, Controls on the Back of the Generator). The color in the arrow moves from left to right to indicate that the test is running. The numbers on the screen are the values being sent to the recording system.
		STOP	Press **STOP** to stop the transmission test.
Pump	• Active flow rate (or dashes if the pump is not connected) • Serial number (or dashes if the pump is not connected) • Message to connect the pump and select an irrigated catheter preset (if the pump is not connected or if a non-irrigated catheter preset is selected.)	**Flush** (active when the pump is connected)	Press **Flush**. When a message appears, press and hold the **Data Entry Knob** to flush air bubbles from the irrigation tubing and the catheter. Use this function carefully! For details, see Section 6.1.5, Data Entry Knob.
		START Low Flow (visible when the pump is connected and is stopped)	Press **START Low Flow** to start the pump flowing at the low (standby) flow rate (see Section 6.3.10, Irrigation Control).
		STOP (visible when the pump is connected and is running)	Press **STOP** to stop the pump.

Table 3 – Device Screens

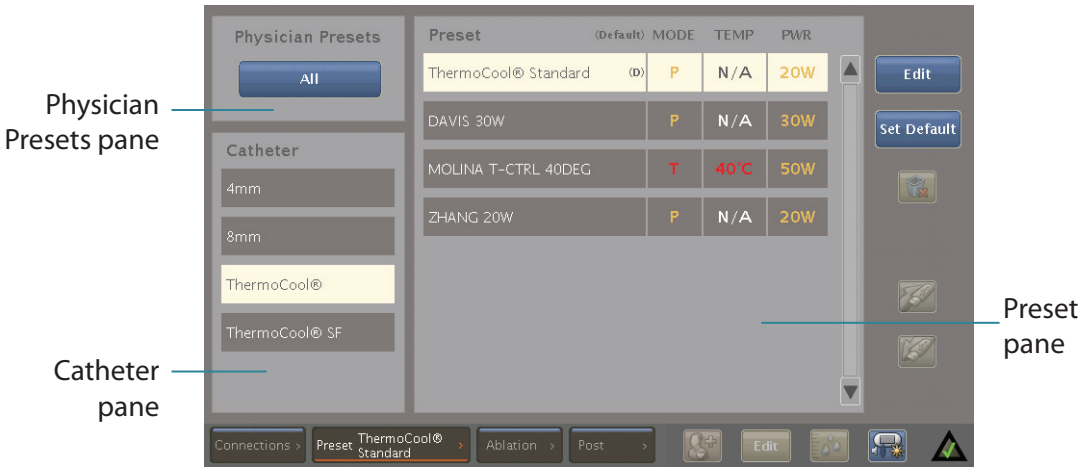
Device	Information Displayed	Action	Action Description
Remote	• Device name • Serial number (or dashes if the remote control is not connected)	N/A	N/A
Foot Pedal	• Image of foot pedal	Foot pedal test (for the foot pedal connected to the generator)	Press the foot pedal connected to the generator to verify that it is working. During the foot pedal test, a tone is emitted and the image changes to a pressed foot pedal. RF energy is not delivered during the foot pedal test (while the Foot Pedal device screen is displayed).
Indifferent Electrode	• Green bar and number(s) indicating impedance if indifferent electrode is connected and is functioning properly • Red bar and dashes if indifferent electrode is not connected • Red bar and number(s) if split indifferent electrode is connected but contact quality is below the threshold	N/A	N/A
Esophageal Probe *(not applicable for the US and JP versions of the generator)*	• Temperature of esophageal probe (or dashes if there is no probe attached) • Connection status	N/A	N/A
Catheter	• Type of catheter selected on **PRESET** screen • Connection status	N/A	See Section 6.3.2, Selecting a Preset.

Table 4 – System Settings Screen Options

Information Displayed	Action
Date	Press a gray date button and use the **Data Entry Knob** to change the date.
Time	Press a gray time button and use the **Data Entry Knob** to change the time.
Language	Select a language (if supported by the software version).
Calibrate Touch Screen button	Press **Calibrate Touch Screen** to improve the performance of the touch screen (see Section 7.5, Calibrating the Touch Screen).
Service button	This button is for use by service technicians.
Export to USB button	Press **Export to USB** to export ablation and event log data to a USB flash drive (see Section 6.5.1, Exporting Ablation and Event Log Data to a USB Flash Drive).

6.3 Presets

PRESET Screen



6.3.1 Preset Overview

- A preset is a named group of settings to use during ablation.
- The SmartAblate™ RF Generator comes with one standard preset for each catheter type listed in the Catheter pane. This preset is always the first in the list and it cannot be deleted.
- You can create new presets for each physician.
- You can view a list of all of the presets for a selected catheter type, or you can view only the presets for a selected physician for the selected catheter type.
- When you select a catheter type, the default for that catheter type is automatically selected. You can designate one of the displayed presets to be the new default for the catheter type.

6.3.2 Selecting a Preset

Quick Steps

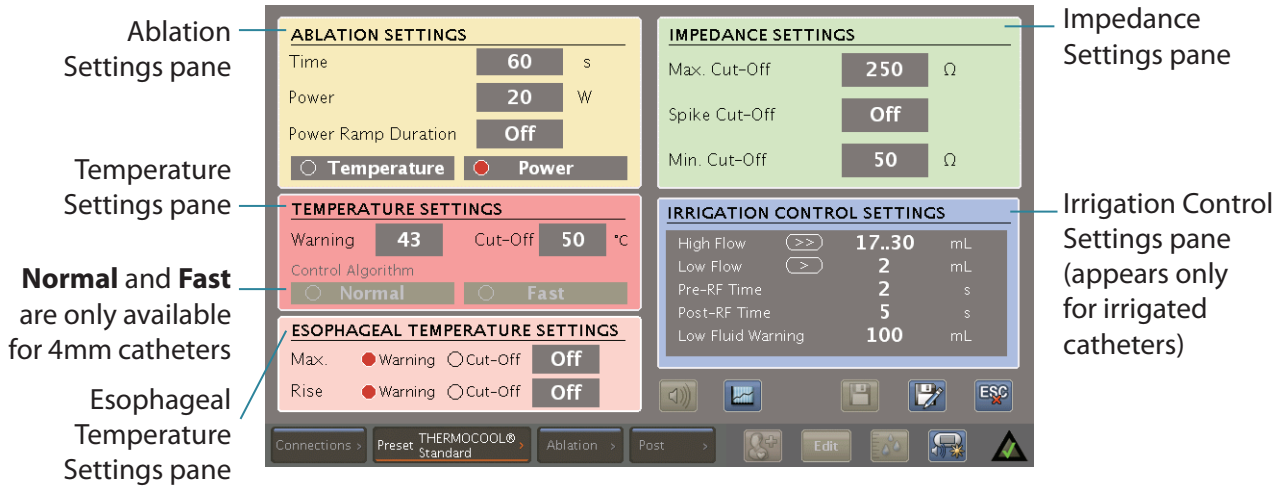
- Press the **PRESET** workflow button.
- Select the catheter type.
- Select a preset.

Notes

1. The currently selected preset is highlighted (white background).
2. The **PRESET** workflow button displays the name of the selected preset.
3. For instructions on displaying the presets for only one physician, see Section 6.3.8, Displaying One Physician's Presets.

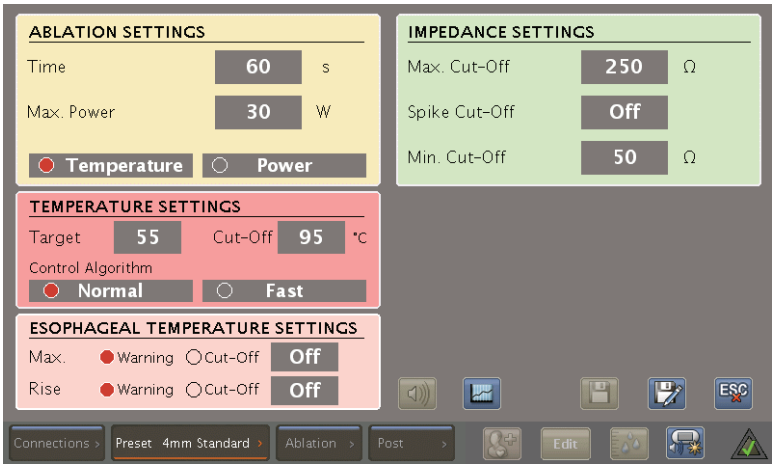
6.3.3 Editing a Preset

Edit Preset Screen in Power Control Mode, Irrigated Catheter



(The Esophageal Temperature Settings pane shown above is not applicable for the US and JP versions of the generator.)

Edit Preset Screen in Temperature Control Mode, Non-Irrigated Catheter *



* Temperature Control Mode is not available for some irrigated catheters.

(Temperature Control Mode for irrigated catheters and the Esophageal Temperature Settings pane are not applicable for the US and JP versions of the generator.)

EDITING A PRESET (continued)

Quick Steps

1) Display the Edit Preset Screen

- Press the **PRESET** workflow button.
- Select the preset to edit.
- Press **Edit**.

2) Change the Control Mode (not available for all catheter types)

- In the Ablation Settings pane, select **Temperature** or **Power**.

3) Change Settings

- Press a displayed value (see Table 5 – Preset Setting Descriptions in this section).
- Use the **Data Entry Knob** to change the value (see Section 6.1.5, Data Entry Knob).
- Press **Save**, then press **In selected preset**.
  or
  Press **Escape**, then press **No** to exit the screen without changing the preset.

Notes

1. If you don't see the preset that you want to edit, select a different catheter type (see Section 6.3.2, Selecting a Preset) or display the presets for a different physician (see Section 6.3.8, Displaying One Physician's Presets).
2. The choices in each pane vary depending on the catheter type you select.
3. Before making changes, select **Temperature** or **Power** in the Ablation Settings pane to select Temperature Control Mode or Power Control Mode. The selections in the panes vary depending on the mode.

   (Temperature Control Mode is not available for all catheter types and is not applicable for the US and JP versions of the generator.)
4. The Irrigation Control Settings pane appears only when you select an irrigated catheter.
5. When you press **Save**, a message appears asking whether to save **In selected preset** or **Save temporarily**. Select **In selected preset**. (See Section 6.3.4, Editing a Preset – Temporary Save, for information on **Save temporarily**.)
6. When you press **Save** and then press **In selected preset**, the selected preset is saved with the revised values. If you want to save the revisions as a different preset, press **Save As** and follow the instructions in Section 6.3.5, Creating a New Preset.
7. You cannot save changes to the standard presets that come with the generator. If you make changes to a standard preset and want to save the changes, press **Save As** and follow the instructions in Section 6.3.5, Creating a New Preset.

Table 5 – Preset Setting Descriptions

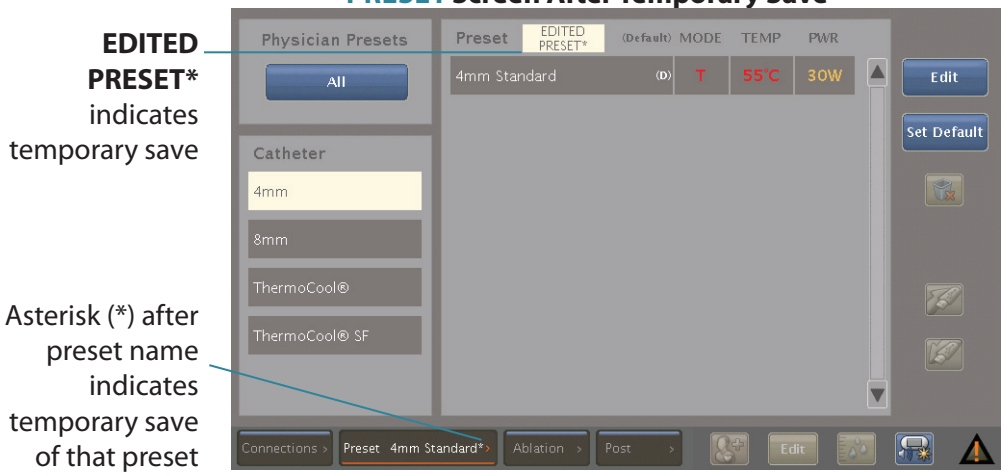
Setting	Description
Ablation Settings Pane	
Time	The time limit for a single ablation. Ablation will stop automatically after this time.
Max. Power	(only in Temperature Control Mode) Upper power limit for the temperature control algorithm. The temperature control algorithm will automatically set the power without exceeding this value. Consult the instructions for use for the catheter to determine the appropriate power setting for the catheter.
Power	(only in Power Control Mode) The output power to be maintained by the generator during the ablation. Consult the instructions for use for the catheter to determine the appropriate power setting for the catheter.
Power Ramp Duration	(only in Power Control Mode) The time it will take the generator to increase power from 0W to the value set in the **Power** field.
Temperature Settings Pane	
Target	(only in Temperature Control Mode) The temperature that you want the ablation electrode to reach. The generator will generate power up to the **Max. Power** setting in an attempt to reach the **Target** temperature.
Warning	(only in Power Control Mode) The temperature of the ablation electrode at which a warning will occur. RF energy will remain on.
Cut-Off	The temperature of the ablation electrode at which RF energy will automatically shut off.
Control Algorithm	(only for 4mm catheters in Temperature Control Mode) The sensitivity of the temperature control algorithm to changes in temperature; how fast it reacts/how aggressively it changes the power to reach the target temperature.
Esophageal Temperature Settings Pane *(not applicable for the US and JP versions of the generator)*	
Max. Warning / Cut-Off	Select either **Warning** or **Cut-Off**. If you select **Warning**, then select the temperature of the esophageal probe at which you want a warning to occur. RF energy will remain on. If you select **Cut-Off**, then select the temperature of the esophageal probe at which RF energy will automatically shut off.

Table 5 – Preset Setting Descriptions

	Setting	Description
	Rise Warning / Cut-Off	Select either **Warning** or **Cut-Off.** If you select **Warning**, then select the increase of temperature of the esophageal probe at which you want a warning to occur during ablation—the increase will be determined from a baseline measurement taken just before ablation. RF energy will remain on. If you select **Cut-Off**, then select the increase of temperature of the esophageal probe at which RF energy will automatically shut off—the increase will be determined from a baseline measurement taken just before ablation.
Impedance Settings Pane		
	Max. Cut-Off	The maximum impedance measurement between the ablation electrode and the indifferent electrode above which RF energy will automatically shut off.
	Spike Cut-Off	If the impedance spikes higher than the number set here in any half second interval, the RF energy will automatically shut off.
	Min. Cut-Off	The lowest impedance measurement between the ablation electrode and indifferent electrode below which the RF energy will automatically shut off.
Irrigation Control Settings Pane		
	This pane appears only when an irrigated catheter type is selected (see Section 6.3.10, Irrigation Control).	
Other		
	Audio Settings	See Section 6.3.11, Changing Audio Settings.
	Display Settings	See Section 6.3.12, Selecting Ablation Display Settings.

6.3.4 Editing a Preset – Temporary Save

PRESET Screen After Temporary Save



Quick Steps

1) Display the Edit Preset Screen

- Press the **PRESET** workflow button.
- Select the preset to edit.
- Press **Edit**.

or

- When the **ABLATION** screen is displayed, press **Edit** on the Navigation Bar.

2) Edit the Preset

- Follow the instructions in Section 6.3.3, Editing a Preset.

3) Save the Preset Temporarily

- Press the **ABLATION** workflow button or another workflow button.

or

- Press **Save** , then press **Save temporarily**.

Notes

1. When you save temporarily, "**EDITED PRESET***" is displayed above the list of presets and none of the presets in the list is selected. To understand which preset has been temporarily edited, look at the name of the preset on the **PRESET** workflow button—the name will be followed by an asterisk (*).
2. Temporary changes are in effect only until a different preset is selected or the system is turned off. When a different preset is selected, the temporary changes to the previous preset are discarded.
3. The most common time to perform a temporary save is when you are preparing to start ablation or during a pause in ablation when you determine that a permanently saved preset does not contain the exact settings that you want.
4. To save the temporary preset as a new preset, follow the instructions in Section 6.3.5, Creating a New Preset.
5. All changes made at the **ABLATION** screen are temporary (see Section 6.4.3, Making Temporary Changes to Ablation Settings).

6.3.5 Creating a New Preset

Keyboard Screen

Quick Steps

- Press the **PRESET** workflow button.
- In the Catheter pane, select the catheter type for which you want to create a preset.
- In the Preset pane, select a preset with settings similar to those you want.
- Press **Edit**.
- Change the settings (see Section 6.3.3, Editing a Preset).
- Press **Save As**.
- Select a physician's name, then type a preset name.
  or
  Press **Create New**, type a physician name, press **PRESET NAME**, then type a preset name.
- Press **OK**.

Notes

1. The physician's name can be a maximum of 9 characters.
2. The maximum number of physician names is 10.
3. The preset name can be a maximum of 13 characters.
4. The maximum number of presets is 80.
5. You cannot use the same preset name for two catheter types. For example, you cannot create an 8mm preset named "20W POWER LIMIT" if you already created one with the same name for 4mm. For this reason, it is a good idea to include a catheter description such as "4MM" in the preset name.
6. If there are fewer than 10 physician names in the Physician Presets list, the physician's name that you type when you create a new preset will be added to the Physician Presets list (see Section 6.3.8, Displaying One Physician's Presets).

7. When you create a new preset, it will be available only for the catheter type that you selected when you created the preset.
8. See Section 6.3.4, Editing a Preset – Temporary Save, for an explanation of a temporary save.

6.3.6 Designating a Default Preset

Quick Steps

- Select the preset that you want as the default.
- Press **Set Default.**

Notes

1. The default preset is the preset that is automatically selected after you select a catheter type.
2. "(D)" appears after the name of the default preset.

6.3.7 Deleting a Preset

Quick Steps

- Select the preset to delete.
- Press **Delete** .
- Press **Yes**.

Notes

1. The standard presets that come with the generator cannot be deleted.
2. If you delete all of the presets for one physician, the physician's name will be deleted from the Physician Presets list (see Section 6.3.8, Displaying One Physician's Presets).

6.3.8 Displaying One Physician's Presets

Quick Steps

- Press the **PRESET** workflow button.
- Select the catheter type.
- In the Physician Presets pane, press the button.
- Select the physician whose presets you want to see.

Notes

1. When the button in the Physician Presets pane says **All**, all of the presets for the catheter type that you selected appear in the Preset pane. When the button says the name of a physician, only the presets for that physician for the selected catheter type (and the standard preset for the selected catheter type) appear.
2. If a physician's name is not listed on the Physician Presets screen, there are no presets associated with that name (see Section 6.3.9, Adding a Name to the Physician Presets List).

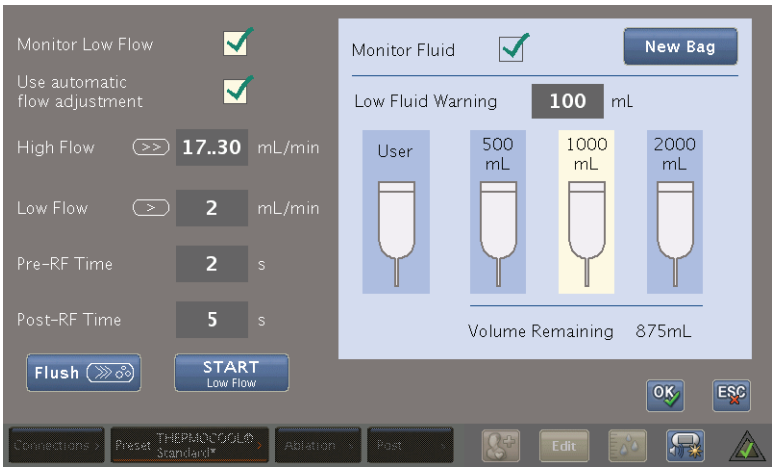
6.3.9 Adding a Name to the Physician Presets List

Quick Step Create a new preset containing the physician's name (see Section 6.3.5, Creating a New Preset).

Note When you create a new preset, you are prompted to select an existing physician's name or type a new physician's name. If there are fewer than 10 physician names in the Physician Presets list when you type a new physician's name, that name will appear automatically in the list the next time that you press the button in the Physician Presets pane (see Section 6.3.8, Displaying One Physician's Presets).

6.3.10 Irrigation Control

Irrigation Control Screen



Quick Steps

1) Display the Irrigation Control Screen

- Press the **PRESET** workflow button.
- Select an irrigated catheter type.
- Select a preset to edit.
- Press **Edit**.
- Press the gray rectangle in the Irrigation Control Settings pane.

or

- Press the **ABLATION** workflow button.
- Press the **Irrigation Control** icon on the Navigation Bar.

2) Change Settings

- Use the **Data Entry Knob** to change values (see Section 6.1.5, Data Entry Knob).
- Press **OK**.
- See Table 6 – Irrigation Control Settings in this section.

Table 6 – Irrigation Control Settings

Setting	Description
Monitor Low Flow	Select **Monitor Low Flow** if you want the system to warn you when either the catheter is in the patient and the pump hasn't started working yet or the flow is stopped.
Use automatic flow adjustment	Select **Use automatic flow adjustment** if you want the rate at which fluid flows during ablation to be automatically adjusted by the system. When **Use automatic flow adjustment** is selected, you will see "AUTO" (automatic) next to the set flow rate on the **ABLATION** screen. When **Use automatic flow adjustment** is not selected, you will see "MAN" (manual) next to the set flow rate on the **ABLATION** screen. (See Section 6.4, Ablation, for a sample screen.) **Note:** If the flow rate is changed manually during ablation as described in Section 6.4.3, Making Temporary Changes to Ablation Settings, all system controls over the flow rate are disabled. The user is responsible for ensuring that the flow rate is appropriate for the power setting.
High Flow	The rate at which fluid flows during Pre-RF, Post-RF, and ablation. If **Use automatic flow adjustment** is selected, press **High Flow** to access the High Flow screen, where you can set the flow for each power increment displayed on a graph. If **Use automatic flow adjustment** is not selected, press **High Flow** and turn the **Data Entry Knob** to change the value. Consult the instructions for use for the catheter to determine the appropriate flow rate for the catheter.
Low Flow	The standby rate at which fluid flows before the Pre-RF period and after the Post-RF period.
Pre-RF Time	The length of time, after **Ablation Start** is pressed, that fluid flows at the **High Flow** (ablation flow) rate without RF. After this **Pre-RF Time**, RF turns on. A tone is emitted during the Pre-RF time.
Post-RF Time	The length of time, after RF turns off, that fluid flows at the **High Flow** (ablation flow) rate. After the **Post-RF Time**, flow returns to the **Low Flow** (standby flow) rate. A tone is emitted during the Post-RF time.
Monitor Fluid	Select **Monitor Fluid** if you want the generator to issue a warning when the fluid level is low. Then specify the size of the bag that you are using. Press **500 mL**, **1000 mL**, or **2000 mL**. Or press **User**, then press the size that appears under **User**, and then use the **Data Entry Knob** to set a different bag size.
Low Fluid Warning	The fluid level at which a warning will occur. **Low Fluid Warning** is only available when **Monitor Fluid** is selected.
New Bag	After you attach a new bag to the pump and select the new bag size on the screen, press **New Bag**.
Volume Remaining	After you press **New Bag**, the generator's fluid level monitor will reset and the new bag size will appear after **Volume Remaining**.

Table 6 – Irrigation Control Settings

Setting	Description
Flush	Press **Flush**. When a message appears, press and hold the **Data Entry Knob** to flush air bubbles from the irrigation tubing and the catheter. Use this function carefully! For details, see Section 6.6, Flushing to Eliminate Air in the Tubing and Catheter.
START Low Flow (visible only when the pump is stopped)	Press **START Low Flow** to start the pump rotation at the **Low Flow** (standby flow) rate.
STOP (visible only when the pump is running)	Press **STOP** to stop the pump.

6.3.11 Changing Audio Settings

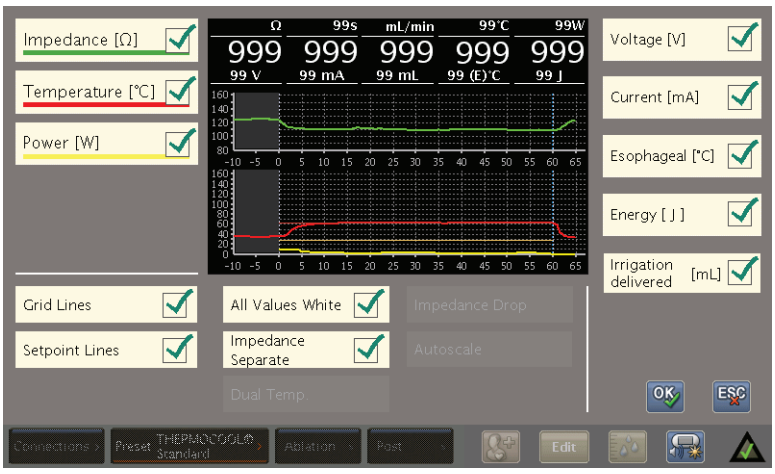
Quick Steps

- Press the **PRESET** workflow button.
- Press **Edit**.
- Press **Audio Settings**.
- Select the options that you want.
- Press **OK**.

Note This feature is not available in some software versions.

6.3.12 Selecting Ablation Display Settings

Display Settings Screen



(The Esophageal (°C) selection shown above is not applicable for the US and JP versions of the generator.)

Quick Steps

- Press the **PRESET** workflow button.
- Press **Edit**.
- Press **Display Settings** .
- Select the options that you want.
- Press **OK** .

Notes

1. The options that you select determine what is displayed on the screen during ablation (see Section 6.4, Ablation).
2. The **Irrigation Delivered** option is displayed only for irrigated catheters. This value is the total irrigation delivered during the procedure, excluding flushing.
3. The **Dual Temp** option is displayed only for dual sensor (DS) 8mm catheters.

6.3.13 Copying Presets to a USB Flash Drive

Quick Steps

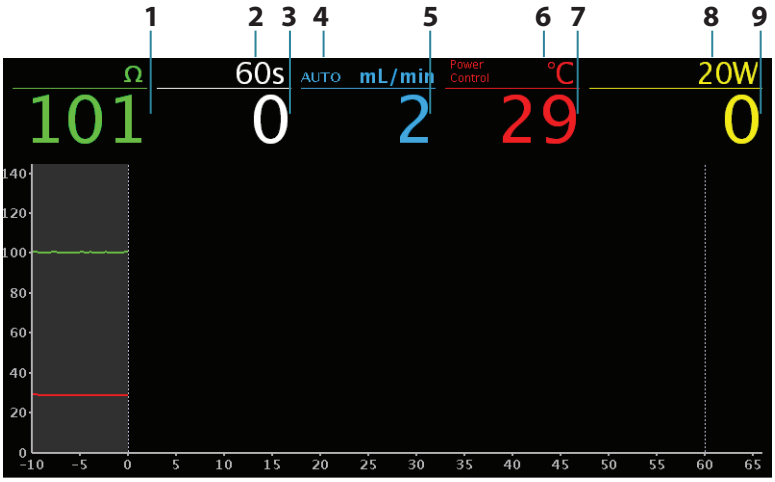
- Press the **PRESET** workflow button.
- Press **To USB** .

Note

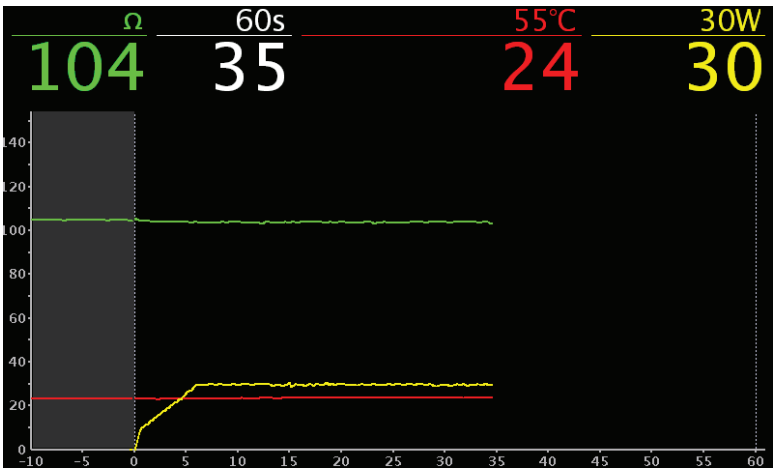
This feature is not available in some software versions.

6.4 Ablation

ABLATION Screen in Power Control Mode (before ablation starts)



ABLATION Screen in Temperature Control Mode (during ablation)



(Temperature Control Mode for irrigated catheters is not applicable for the US and JP versions of the generator.)

Item	Description
1	Impedance measurement
2	Set time
3	Time since start of ablation
4	Flow rate control indicator (AUTO = automatic, MAN = manual)
5	Set flow rate
6	Set temperature (displayed only in Temperature Control Mode)
7	Measured temperature
8	Set power (in Power Control Mode) Max. power (in Temperature Control Mode)
9	Measured real power output

6.4.1 Starting a New Procedure

Quick Steps

- Press the **ABLATION** workflow button.
- Press **New Procedure** on the Navigation Bar.
- Press **Yes**.
- On the **PRESET** screen, select a preset.

Notes

1. When you start a new procedure, any accumulated parameters are reset and all new data is logged as part of the new procedure. The **POST** screen summarizes the activities (see Section 6.5, Post Procedure).
2. If the generator is off for more than 6 hours, a new procedure starts automatically when you turn on the generator and start ablation.

6.4.2 Starting and Stopping Ablation

Quick Steps

- Press the **ABLATION** workflow button.
- To start ablation, press **Ablation Start** on the front of the generator or remote control (or press and hold the foot pedal).
- To stop ablation, press **Stop** on the front of the generator or remote control (or release the foot pedal).

Notes

1. Either the generator or the remote control can be the system Master (see Section 6.7, System Control). When the remote control is the system Master, ablation can still be started from the generator.
2. When you start ablation, the **RF On** indicator on the generator and on the remote control light up and a continuous tone is emitted. These turn off when you stop ablation.
3. If a Pre-RF time has been set for fluid control, RF energy will not start until after the fluid has flowed for the Pre-RF amount of time (see Section 6.3.10, Irrigation Control).
4. If ablation does not stop when you press **Stop** , try any of these alternatives:
   - If you pressed **Stop** on the generator, press **Stop** on the remote control.
   - If you pressed **Stop** on the remote control, press **Stop** on the generator.
   - Press and release the foot pedal on the generator.
   - Press and release the foot pedal on the remote control.
   - Press **Stand-by** on the generator.
   - If the remote control is the system Master, press **Stand-by** on the remote control.
   - Disconnect any of the following cables: catheter connection cable, indifferent electrode connection cable, mains cable.

5. During ablation, the Navigation Bar disappears. After ablation, the Navigation Bar reappears.
6. For irrigated catheters, if the fluid level reaches the **Low Fluid Warning** level, the **Irrigation Control** icon appears at the bottom of the **ABLATION** screen as a warning. After ablation stops and the Navigation Bar appears, press the **Irrigation Control** icon to access the Irrigation Control screen (see Sections 6.3.10, Irrigation Control, and 6.4.5, Low Fluid Level).
7. Ablation stops if conditions are not right for ablation (see Section 7.2, Warnings, Alerts, and Ablation Stop Reasons).
8. A few seconds after you stop ablation, the Ablation Summary appears (see Section 6.4.4, Ablation Summary).
9. To minimize the risk to the patient, keep the ablation duration to one minute or less.

6.4.3 Making Temporary Changes to Ablation Settings

Quick Steps

To Change Values at the Top of the Ablation Screen

- Press the displayed value.
- Turn the **Data Entry Knob** to change the value.

To Change Values at the Edit Preset Screen

- See Section 6.3.4, Editing a Preset – Temporary Save.

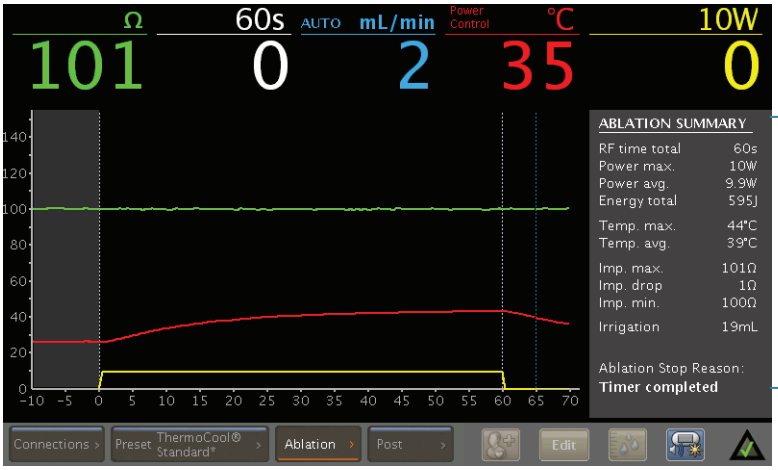
Notes

1. The ablation values that are displayed when you first access the **ABLATION** screen are determined by the selected preset for the catheter type—either the default preset or a preset that you selected (see Sections 6.3.2, Selecting a Preset, and 6.3.3, Editing a Preset).
2. When Power Control Mode is selected in the preset, "Power Control" is displayed at the top of the screen. (See the sample screen in Section 6.4, Ablation.)
3. On the **ABLATION** screen, before or during ablation, you can change the time (s) and power (W) values. In Temperature Control Mode, you can also change the temperature set point (°C). For irrigated catheters, you can also change the flow rate (mL/min). These changes take effect immediately, without confirmation.
4. When you change the flow rate on the **ABLATION** screen, "AUTO" at the top of the screen changes to "MAN." It reverts to "AUTO" at the end of the current ablation.
5. All changes made as described above are temporary. An asterisk (*) appears after the preset name on the **PRESET** workflow button to indicate that temporary changes have been made but have not been saved. The changes stay in effect until a different preset is selected or until the system is turned off. If you want to save these settings in a new preset, follow the steps in Section 6.3.5, Creating a New Preset.

6. The catheter type selected for the preset imposes restrictions on the flow rate and the ranges of power. Consult the instructions for use for the catheter to determine the appropriate flow rate and power.

6.4.4 Ablation Summary

Ablation Summary



Notes

1. A few seconds after ablation stops, the Ablation Summary appears.
2. At the bottom of the Ablation Summary, an Ablation Stop Reason is displayed (see Section 7.2, Warnings, Alerts, and Ablation Stop Reasons).
3. To remove the trend lines and the Ablation Summary, either wait for them to disappear or press anywhere on the screen.
4. To view a summary of the entire procedure, press the **POST** workflow button (see Section 6.5, Post Procedure).

6.4.5 Low Fluid Level

Quick Steps

To Change the Fluid Level Settings for a Preset

- See Section 6.3.10, Irrigation Control.

To Indicate Replacement of the Fluid Bag

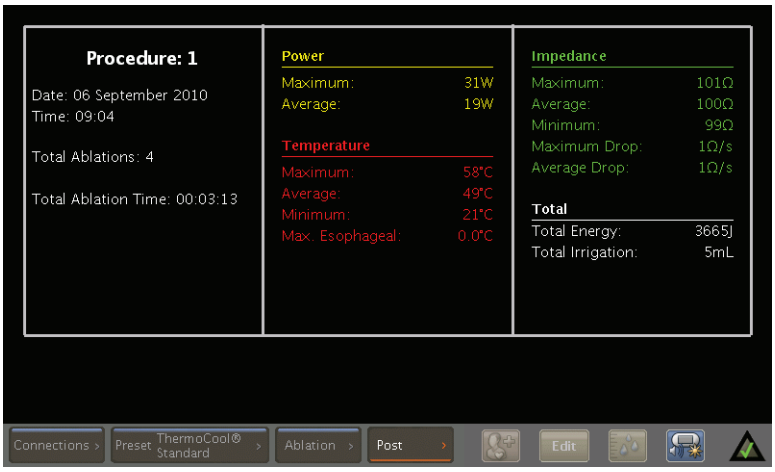
- Wait until ablation stops (or press **Stop**).
- Press **Irrigation Control**.
- If the bag size changed, select the new bag size (see Section 6.3.10, Irrigation Control).
- Press **New Bag**.
- Press **OK**.
- Press the **ABLATION** workflow button.

Notes

1. The generator calculates the amount of fluid delivered and estimates the remaining fluid amount based on the bag size you select. When you press **New Bag**, the remaining fluid level is reset to be the same as the bag size you select. Because the volume remaining calculation is affected by the preset you select, the value of the remaining volume may not correctly reflect the actual volume remaining if you select a different preset during an ablation.
2. When you turn off the generator and turn it on again within 6 hours, the volume remaining value is retained. If you turn the generator on again after 6 hours, the volume remaining is reset to the selected bag size.
3. Before you start ablation, the **Irrigation Control** icon is available on the Navigation Bar. After you start ablation, the Navigation Bar disappears. During ablation, if the fluid level reaches the warning limit set on the Irrigation Control screen, the **Irrigation Control** icon appears at the bottom of the **ABLATION** screen with a flashing orange border.
4. If you press **Irrigation Control** when the **ABLATION** screen is displayed and you then make changes on the Irrigation Control screen, an asterisk (*) appears after the name of the preset on the **PRESET** workflow button to indicate that temporary changes have been made (see Section 6.4.3, Making Temporary Changes to Ablation Settings).
5. The Irrigation Control screen indicates the volume remaining in the selected bag size. When you press **New Bag**, this number resets to the selected bag size.

6.5 Post Procedure

POST Screen



(The Max. Esophageal temperature shown above is not applicable for the US and JP versions of the generator.)

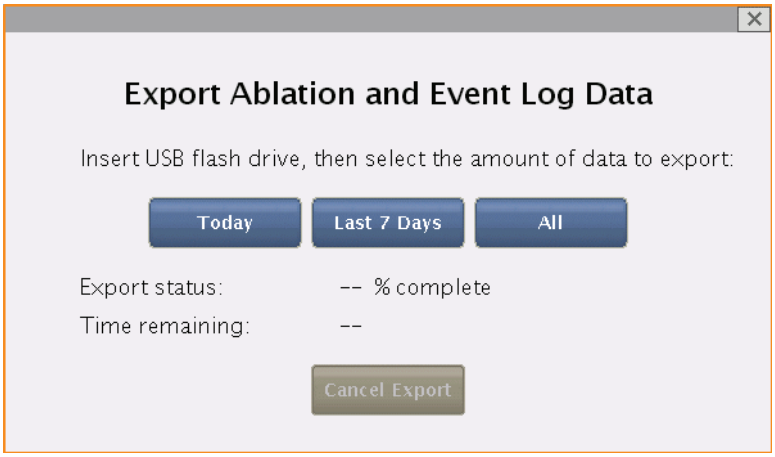
Quick Step

Press the **POST** workflow button.

Notes

1. The **POST** screen displays a summary of the data collected by the generator during an entire procedure. To indicate the start of a new procedure (to restart data collection), press **New Procedure** (see 6.4.1, Starting a New Procedure).
2. The **Total Irrigation** value shown on the **POST** screen is the total irrigation delivered during the procedure, excluding flushing.

6.5.1 Exporting Ablation and Event Log Data to a USB Flash Drive


Export Ablation and Event Log Data
Insert USB flash drive, then select the amount of data to export:
Today
Last 7 Days
All
Export status: -- % complete
Time remaining: --
Cancel Export

Quick Steps

- Insert a USB flash drive into the USB port on the back of the generator.
- Press the **CONNECTIONS** workflow button.
- Press **System Settings** .
- Press **Export to USB**.
- Press **Today**, **Last 7 Days**, or **All**.
- When the export status is 100% complete, remove the USB flash drive.

Notes

1. The USB port is located on the back of the generator (see Item 2 in Section 4.3, Controls on the Back of the Generator).
2. If you press **Today**, all data from the current day will be exported. If you press **Last 7 Days**, all data from the last 7 days will be exported. If you press **All**, all data on the generator will be exported. These buttons change from blue to gray during the export process.
3. A light green dot appears on the export status line and continually gets darker as the export process progresses. It changes to when the export status is 100% complete. It changes to if you press **Cancel export** or if the export fails. Any files that have already been exported to the USB flash drive, will remain on the flash drive. Any file that was only partially exported, will be completely exported the next time the export process is started.
4. The export process may take minutes or more than an hour depending on the amount of data.

6.6 Flushing to Eliminate Air in the Tubing and Catheter

WARNINGS

- Irrigated catheters must be flushed before they are inserted in the patient.
- When flushing a catheter, the catheter must not be inside the patient. When flushing the SmartAblate™ Irrigation Tubing Set, either the catheter must be outside the patient or the 4-way stopcock on the tubing set must be turned so that the fluid is not routed to the catheter.

Quick Steps

- Ensure that the catheter is not in the patient (or that the 4-way stopcock on the tubing is turned so fluid is not routed to the catheter).
- Open the Pump device screen or the Irrigation Control screen.
- Press **Flush** on the screen or **Flush** on the pump.
- When a message appears, press and hold the **Data Entry Knob** .
- Release the **Data Entry Knob** .

Notes

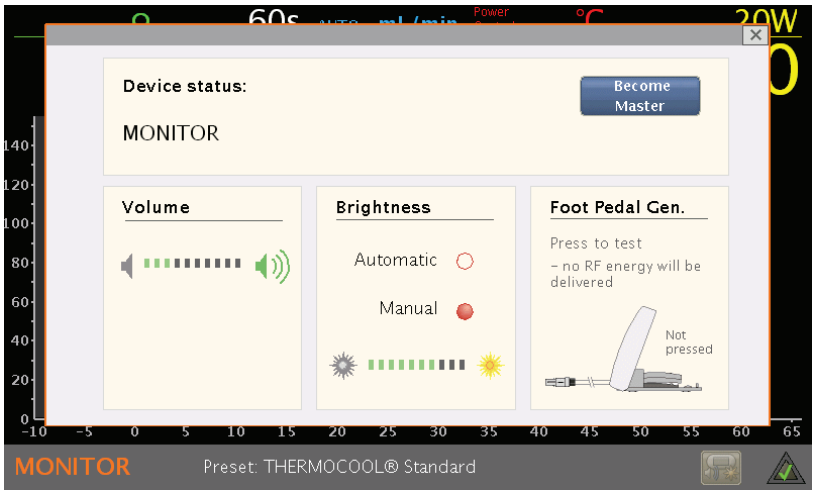
1. The **Flush** button is available on the generator's Pump device screen (see Table 3 – Device Screens in Section 6.2) and on the Irrigation Control screen (see Section 6.3.10, Irrigation Control).
2. To ensure that all bubbles have been flushed from the catheter or tubing set, flush for at least 5 additional seconds after an image appears on the pump's display indicating that no bubbles were detected and after there are no visible bubbles in the tubing (see the instructions for use provided with the pump).
3. Opening the door of the pump can move the tubing slightly, causing the bubbles to move out of the bubble sensor area. Inspect the tubing carefully!

6.7 System Control

When you first turn on the generator, the generator is the system Master and the remote control is the Monitor. The Master controls all system functions (except the volume, brightness, and foot pedal testing of the Monitor). At the remote control, you can request that it become the Master (the generator then becomes the Monitor). When you want the generator to take control again, make it the Master as described in this section.

Note: Screen calibration also affects only the Master (see Section 7.5, Calibrating the Touch Screen).

System Control Screen (When Generator Is Monitor)



MONITOR

6.7.1 Making the Generator the System Master

Quick Steps

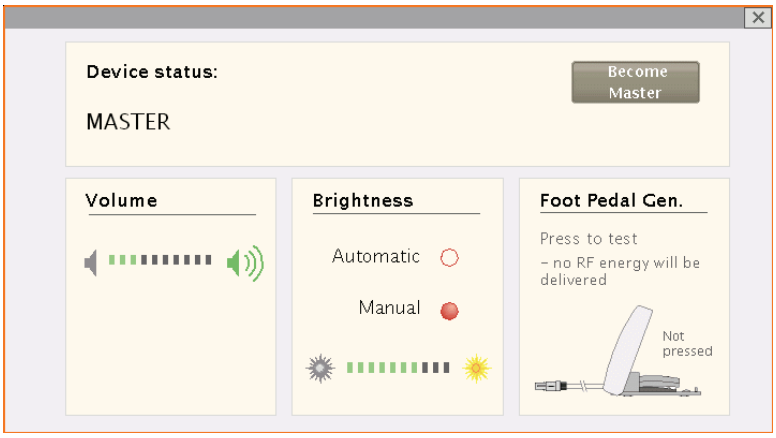
- Press **System Control** on the Navigation Bar.
- Press **Become Master**.

Notes

1. The **Ablation Start** button on the generator and the foot pedal on the generator can be used to start ablation regardless of whether the generator is the Master or the Monitor. Similarly, the **Stop** button and the foot pedal on the generator can be used to stop ablation, regardless of whether the generator is the Master or the Monitor.
2. When the remote control is the Monitor, it can only be used to stop ablation.

6.8 Volume, Brightness, and Foot Pedal Test

System Control Screen



Quick Steps

Press **System Control** on the Navigation Bar to open the System Control screen.

Volume

- Press the volume bar, then turn the **Data Entry Knob** to change the volume of the audio output.

Brightness

- Select **Automatic** to have the system determine the screen brightness.
- Select **Manual**, then press the brightness bar and turn the **Data Entry Knob** to adjust the screen brightness manually.

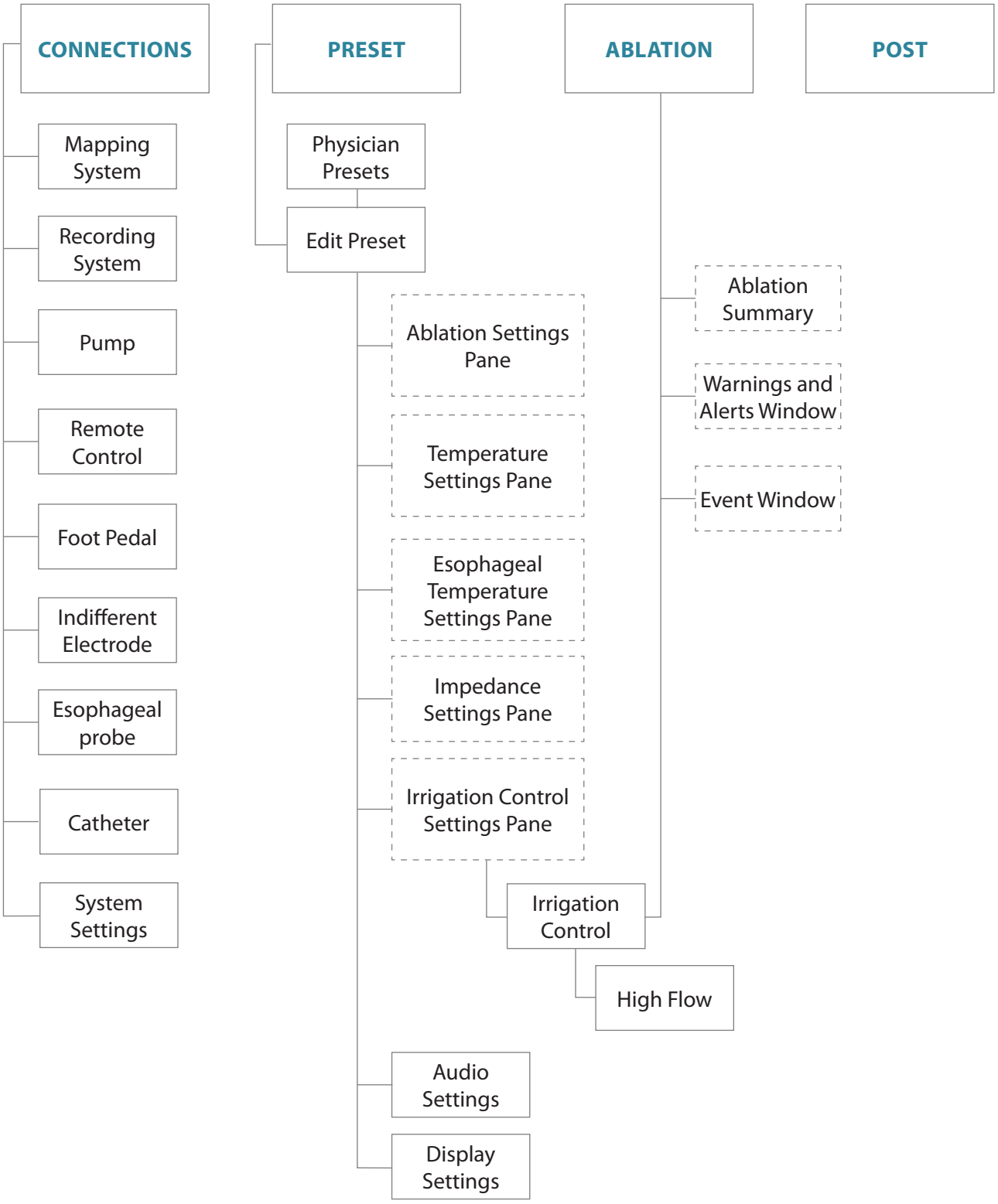
Foot Pedal

- Press the foot pedal connected to the generator to verify that it is working. During the foot pedal test, a tone is emitted and the image changes to a pressed foot pedal. RF energy is not delivered during the foot pedal test (while the System Control screen is displayed).

Notes

1. This screen is displayed only on the local unit (generator or remote control) and the settings affect only the local unit. The local unit can be the system Master or the System monitor when you access this screen. (See Section 6.7, System Control for information about the system Master.)
2. The volume setting affects the RF tone and all alarm and informational tones. Make sure that you select the appropriate volume so that you can hear the tones.
3. When the generator is the system Master, you can also perform the foot pedal test on the Foot Pedal device screen, which is accessible from the **CONNECTIONS** screen (see Table 3 – Device Screens, in Section 6.2, Connections).

6.9 Flowchart of the Screens



(The Esophageal Probe and the Esophageal Temperature Settings Pane shown above are not applicable for the US and JP versions of the generator.)

6.10 Icons on the Screens

Name	Icon	Where	Manual Section
Audio Settings		Edit Preset screen	6.3.11, Changing Audio Settings The icon is gray if this feature is not supported by the software version.
Close		Top right corner of many screens	Press the icon to close the screen.
Delete		**PRESET** screen	6.3.7, Deleting a Preset
Display Settings		Edit Preset screen	6.3.12, Selecting Ablation Display Settings
Escape		Many screens	Press the icon to close the screen without saving changes.
Front/Back		**CONNECTIONS** screen	6.2, Connections
Irrigation Control		Navigation Bar Also appears on the **ABLATION** screen when fluid is low during ablation.	6.3.10, Irrigation Control The icon is gray until the **ABLATION** workflow button is pressed.
New Procedure		Navigation Bar	6.4.1, Starting a New Procedure The icon is gray until the **ABLATION** workflow button is pressed.
OK		Many screens	Press the icon to close the screen and save changes.
Save		Edit Preset screen	6.3.3, Editing a Preset 6.4.3, Making Temporary Changes to Ablation Settings
Save As		Edit Preset screen	6.3.5, Creating a New Preset
System Control		Navigation Bar	6.7, System Control 6.8, Volume, Brightness, and Foot Pedal Test
System Settings		**CONNECTIONS** screen	6.2, Connections
System Status: Ready for Ablation		Navigation Bar	7.2, Warnings, Alerts, and Ablation Stop Reasons

Name	Icon	Where	Manual Section
System Status: Warning or Alert		Navigation Bar	7.2, Warnings, Alerts, and Ablation Stop Reasons
System Status: System Error		Navigation Bar	7.3, System Errors
USB: To USB		**PRESET** screen	6.3, Presets Also see 6.5.1, Exporting Ablation and Event Log Data to a USB Flash Drive. The icon is gray if this feature is not supported by the software version.
USB: From USB		**PRESET** screen	6.3, Presets The icon is gray if this feature is not supported by the software version.
Wait		Many screens	This icon appears when the system is busy.

7 Troubleshooting

7.1 Device Connections

The **CONNECTIONS** screen (see Section 6.2, Connections) displays to indicate that a device is properly connected and to indicate a problem with the connection. Table 7 describes the specific meaning of these icons for each device.

Table 7 – Device Connections

Device	Meaning of Icons		
Pump		Communication between the generator and the SmartAblate™ Irrigation Pump was established and is functional. The pump is now controlled by the generator.	
		Possible Reasons	**What To Do**
		The pump is not connected to the generator.	Connect the pump to the generator.
		The pump is powered off.	Turn on the power to the pump.
		There are communication problems between the generator and the pump.	Replace the communication cable between the generator and the pump.
		The pump has a software version that is not compatible with the generator's software version.	Check the software version on the pump and on the generator. (See Table 3 – Device Screens in Section 6.2.) Then consult Customer Support.
		There may be a problem with the pump, for example, the pump door may be open or there may be a bubble in the irrigation tubing.	See the SmartAblate™ Irrigation Pump User Manual.

Table 7 – Device Connections

Device	Meaning of Icons	
Remote	Communication between the generator and the SmartAblate™ Remote Control was established and is functional.	
	Possible Reasons	**What To Do**
	The remote control is not connected to the generator.	Connect the remote control to the generator.
	The remote control is powered off.	Turn on the power to the remote control.
	There are communication problems between the generator and the remote control.	Replace the communication cable between the generator and the remote control.
	The communication cable between the generator and the remote control is damaged.	Replace the communication cable between the generator and the remote control.
	The remote control has a software version that is not compatible with the generator's software version.	The software version on the remote control needs to be updated. Contact Customer Support.
Foot Pedal	The foot pedal is connected to the generator and has passed the foot pedal test.	
	Possible Reasons	**What To Do**
	The foot pedal is not connected to the generator (or has become disconnected).	Connect the foot pedal to the generator. Perform the foot pedal test. (See Table 3 – Device Screens in Section 6.2 or Section 6.8, Volume, Brightness, and Foot Pedal Test.)
	The foot pedal test has not been performed.	Press the image of the foot pedal and perform the foot pedal test.
	The foot pedal has failed the foot pedal test.	Replace the foot pedal with a good foot pedal and perform the foot pedal test.
	The foot pedal automatic ID check failed.	In this case, although the foot pedal may have passed the foot pedal test, it cannot be used. Replace the foot pedal with a good foot pedal and perform the foot pedal test.

Table 7 – Device Connections

Device	Meaning of Icons	
Indifferent Electrode	Solid indifferent electrode: Indicates that the indifferent electrode is connected to the system. Split indifferent electrode: Indicates that the indifferent electrode is connected to the system and contact with the patient is good enough for ablation.	
	Possible Reasons	**What To Do**
	Solid or split indifferent electrode: The indifferent electrode is not connected to the generator.	Connect the indifferent electrode to the generator.
	Split indifferent electrode: The contact quality on the patient is not good enough for ablation.	Improve the contact of the indifferent electrode on the patient. (See Section 3.4, Handling Indifferent Electrodes.)
Esophageal Probe *(not applicable for the US and JP versions of the generator)*	The esophageal probe is connected to the generator and the temperature is within a reasonable range for the room or for the patient.	
	Possible Reasons	**What To Do**
	The esophageal probe is not connected to the generator.	Verify that the esophageal probe is connected to the appropriate SmartAblate™ System connection cable. (See Section 5.2.3, SmartAblate™ Cables.) Verify that the esophageal probe connection cable is connected to the red **Catheter 2** receptacle on the front of the generator. (See Item 5 in Section 4.2, Controls on the Front of the Generator.)
	The temperature is not within a reasonable range.	Verify that the esophageal probe is compatible with the generator. Verify that the connection cable is correct for the type of esophageal probe.
	The esophageal probe or connection cable is defective.	Replace the esophageal probe and/or connection cable with a new one.

Table 7 – Device Connections

Device	Meaning of Icons	
Catheter (and Ablation Cable to Mapping System, if applicable)	The catheter is connected to the generator and the temperature is within a reasonable range for the room or for the patient.	
	Possible Reasons	**What To Do**
	The catheter is not connected to the generator.	Verify that the **CONNECTIONS** screen reflects the mapping system that you are using (CARTO® 3 System, CARTO® XP System, or other). Verify that the catheter is connected to the appropriate cable and that the cable is connected to the red **Catheter 1** receptacle on the front of the generator. (See Item 4 in Section 4.2, Controls on the Front of the Generator.)
	The wrong cable type is being used.	Verify that you are using the correct catheter connection cables for the selected catheter type and for the selected mapping system. (See Section 5.2.3, SMARTABLATE™ Cables.)
	The catheter or a cable is defective.	Replace the catheter and/or connection cable(s) with new ones.

7.2 Warnings, Alerts, and Ablation Stop Reasons

Warnings and Alerts

The **System Status** icon is visible on the Navigation Bar whenever ablation is not being performed. There are three different **System Status** icons: .

= Ablation can be performed and there are no active Warnings or Alerts.

= There is a Warning or an Alert.

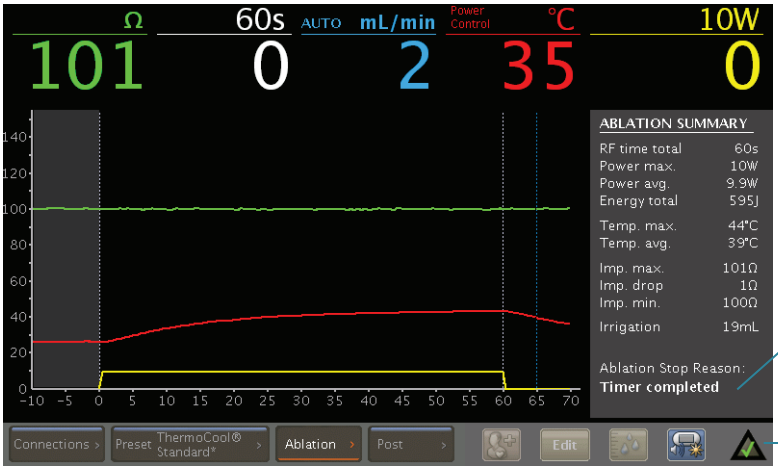
A Warning indicates a condition that is not critical. Ablation can be performed even when there is a Warning. For example, "Low fluid."

An Alert indicates a condition that is critical and must be fixed before ablation can be performed. An Alert may occur when ablation is not being performed or it may stop ablation. For example, "Catheter temperature above maximum."

The **System Status** icon changes from to when a Warning or an Alert occurs. Press the icon to display the Warnings and Alerts window. Resolve the Warning or Alert (see Table 8 – Warnings, Alerts, and Ablation Stop Reasons in this section). As each Warning or Alert is resolved, it disappears from the screen. Press **Close** to remove the Warnings and Alerts window from the screen.

= There is a System Error or a Fatal System Error. The Event window appears. (See Sections 7.3.1, System Error and 7.3.2, Fatal System Error.)

Ablation Summary with Ablation Stop Reason



When ablation stops because the preset ablation time has been reached or because ablation has been intentionally stopped, the **System Status** icon is displayed. The Ablation Summary appears displaying an Ablation Stop Reason such as "Timer completed."

When ablation stops because an Alert has occurred, the **System Status** icon is displayed and the Ablation Summary screen appears displaying an Ablation Stop Reason that explains the Alert. You also have the option of pressing the icon to display the Warnings and Alerts window. Resolve the Alert (see Table 8 – Warnings, Alerts, and Ablation Stop Reasons below) and then press **Close** to remove the Warnings and Alerts window from the screen.

Table 8 describes the Warnings, Alerts, and Ablation Stop Reasons that may appear on the screen.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Bad contact indifferent electrode #		
• When using a split indifferent electrode, the contact quality with the patient's skin has deteriorated since the indifferent electrode was applied to the patient.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary and both indifferent electrode receptacles flash blue for 5 seconds S = Ablation stop tone	• When using a split indifferent electrode, improve the contact of the indifferent electrode with the patient's skin. (See 3.4, Handling Indifferent Electrodes.) • If the problem persists, use a different indifferent electrode or a different cable.
Bubble		
• The pump sensor identified a bubble in the irrigation tubing.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	**!! Patient Danger !!** • Press the **Stop** button on the pump. • Flush the tubing. (See Section 6.6, Flushing to Eliminate Air in the Tubing and Catheter.) • Resume low (standby) flow.
Catheter temperature above maximum		

• The temperature of the catheter ablation electrode exceeded the cut-off value set in the preset. Possible reasons are:
  • The ablation electrode is too hot.
  • The cut-off value is too low.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary and catheter receptacle flashes red for 5 seconds
	S = Ablation stop tone
		• Wait a few seconds for the temperature to drop before restarting ablation.
		• If the problem persists, modify the temperature cut-off value in the preset that was used. (See Section 6.3.3, Editing a Preset.)
		• Consider possible clinical reasons for the ablation electrode to overheat.
		• If the problem persists, contact Customer Support.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message ▪ Reasons	Indicators (V = Visual, S = Sound)	What To Do
Catheter temperature change		
▪ The catheter temperature changed at a rate that was greater than 20 degrees within 200 ms. This may occur when there is electrical interference between the ablation electrode and the temperature sensor.	**Ablation Stop Reason** V = and Ablation Summary and catheter receptacle flashes red for 5 seconds S = Ablation stop tone	▪ Try a different cable or catheter. If the problem persists, contact Customer Support.
Catheter temperature invalid		
▪ The generator does not recognize a valid temperature reading. Possible reasons are: ▪ A catheter is not connected or is connected to the wrong receptacle. ▪ The cable or catheter is faulty. ▪ There is a compatibility problem between the generator and external devices. ▪ There is an internal problem in the generator.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary and catheter receptacle flashes red for 5 seconds S = Ablation stop tone	▪ Verify that the catheter is connected to the appropriate cable and that the cable is connected to the red **Catheter 1** receptacle on the front of the generator. (See Item 4 in Section 4.2, Controls on the Front of the Generator.) ▪ Verify that you are using a catheter and a cable or cables that are compatible with the generator. ▪ Try a different cable or catheter. If the problem persists, contact Customer Support.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Catheter temperature measurement error		

• The generator recognizes a valid temperature reading but the redundant measurement system reflects a reading problem. Possible reasons are:
  • The cable is faulty.
  • There is a compatibility problem between the generator and external devices.
  • There is an internal problem in the generator.
  • For a dual sensor (DS) catheter, the difference between the measurements of the two sensors is too high. This may be caused by a problem with the catheter or the cables.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary and catheter receptacle flashes red for 5 seconds
	S = Ablation stop tone
		• Verify that you are using a catheter and a cable or cables that are compatible with the generator.
		• Try a different cable, or if you are using a dual sensor (DS) catheter, try a different catheter. If the problem persists, contact Customer Support.

Catheter temperature warning		
• The temperature measured by the catheter may have exceeded the warning value set in the preset.	**Warning** V = appears near temperature reading and its orange border flashes S = Warning tone	• Reduce the power setting used for the ablation or stop the ablation. • If it is clinically appropriate, modify the temperature warning value for the preset that was used. (See Section 6.3.3, Editing a Preset.)
Current output too high		
• The generator was trying to deliver a current output that was beyond its intended capability.	**Ablation Stop Reason** V = and Ablation Summary and catheter receptacle flashes red for 5 seconds S = Ablation stop tone	• See the instructions in this table for **Power output too high**.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Esoph. temperature above maximum (*not applicable for the US and JP versions of the generator*)		

• The esophageal probe temperature exceeded the cut-off value set in the preset. Possible reasons are:
  • The ablation is heating the esophagus.
  • The cut-off value is too low.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary and esophageal probe receptacle flashes red for 5 seconds
	S = Ablation stop tone
		• Wait a few seconds for the temperature to drop before restarting ablation.
		• See the instructions in this table for **Esoph. temperature above maximum** (**Warning**).

Esoph. temperature above maximum (*not applicable for the US and JP versions of the generator*)		

• The esophageal probe temperature exceeded the warning value set in the preset. Possible reasons are:
  • The ablation is heating the esophagus.
  • The warning value is too low.
	Warning
	V = appears near esophageal temperature reading and its orange border flashes
	S = Warning tone
		• Reduce the power setting used for the ablation or stop the ablation.
		• If it is clinically appropriate, reposition the catheter farther away from the esophagus.
		• If the problem persists, contact Customer Support.
		• You can disable this warning by setting its value to **Off**. (See Section 6.3.3, Editing a Preset.)

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Esophageal temperature invalid (*not applicable for the US and JP versions of the generator*)		

• The generator did not recognize a valid temperature reading. Possible reasons are:
  • An esophageal probe is not connected or is connected to the wrong receptacle.
  • The cable is faulty.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary and esophageal probe receptacle flashes red for 5 seconds
	S = Ablation stop tone
		• Verify that the esophageal probe is connected to the appropriate cable and that the cable is connected to the red **Catheter 2** receptacle on the front of the generator. (See Item 5 in Section 4.2, Controls on the Front of the Generator.)
		• Verify that you are using a probe and a cable that are compatible with the generator.
		• Try a different cable or probe. If the problem persists, contact Customer Support.
		• In order to continue with the procedure, you can disable the esophageal monitoring feature by setting the warning and cut-off values to **Off**. (See Section 6.3.3, Editing a Preset.)

Esophageal temperature rise (*not applicable for the US and JP versions of the generator*)		
• The esophageal probe temperature rise exceeded the cut-off value set in the preset.	**Ablation Stop Reason** V = and Ablation Summary and esophageal probe receptacle flashes red for 5 seconds S = Ablation stop tone	• See the instructions in this table for **Esoph. temperature above maximum** (**Alert** and **Ablation Stop Reason**).
Esophageal temperature rise (*not applicable for the US and JP versions of the generator*)		
• The esophageal probe temperature rise exceeded the warning value set in the preset.	**Warning** V = appears near esophageal temperature reading and its orange border flashes S = Warning tone	• See the instructions in this table for **Esoph. temperature above maximum** (**Warning**).

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Foot pedal disconnected – Generator (or **Foot pedal disconn. – Generator**)		
• The foot pedal that was connected to the generator when ablation started became disconnected during ablation.	**Warning** V = and orange border around System Control icon flashes for 20 seconds S = Warning tone **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	• Disconnect the foot pedal from the generator, then reconnect it. If the problem persists, either use a different foot pedal or operate the generator using the **Ablation Start** and **Stop** buttons on the generator or remote control.
Foot pedal disconnected – Remote (or **Foot pedal disconn. – Remote**)		
• The foot pedal that was connected to the remote control when ablation started became disconnected during ablation.	**Warning** V = and orange border around System Control icon flashes for 20 seconds S = Warning tone **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	• Disconnect the foot pedal from the remote control, then reconnect it. If the problem persists, either use a different foot pedal or operate the generator using the **Ablation Start** and **Stop** buttons on the generator or remote control.
Foot pedal released – Generator		
• The pressed foot pedal that is connected to the generator was released.	**Ablation Stop Reason** V = and Ablation Summary S = none	• To resume ablation, press and hold the foot pedal.
Foot pedal released – Remote		
• The pressed foot pedal that is connected to the remote control was released.	**Ablation Stop Reason** V = and Ablation Summary S = none	• To resume ablation, press and hold the foot pedal.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message ▪ Reasons	Indicators (V = Visual, S = Sound)	What To Do
Impedance above maximum		

▪ The impedance exceeded the maximum cut-off value set in the preset. Possible reasons are:
  ▪ The catheter is out of the patient's body or is covered by a sheath.
  ▪ The indifferent electrode has become disconnected from the generator.
  ▪ The indifferent electrode contact with the patient is not good.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary and catheter receptacle flashes red for 5 seconds
	S = Ablation stop tone
		▪ Verify that the catheter is properly inserted in the body and is out of the sheath.
		▪ Disconnect the catheter and the indifferent electrode from the generator, then reconnect them.
		▪ Improve the contact of the indifferent electrode with the patient's skin or use a different indifferent electrode. (See Section 3.4, Handling Indifferent Electrodes.)
		▪ Consider applying the indifferent electrode to a different place on the patient's body to avoid oil, hair, and dirt that increase the impedance.
		▪ If the catheter is connected through an additional system such as a navigation system, make sure that this system is not intentionally disconnecting the generator from the tip of the catheter. Try replacing the system parts that are between the generator and the catheter, or connect the catheter directly to the generator.
		▪ If the problem persists, contact Customer Support.
		▪ It is not recommended, but if you know the reason for the high impedance and still want to perform an ablation, you can disable this cut-off by setting its value to **Off**. (See Section 6.3.3, Editing a Preset.)

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Impedance below minimum		

• The impedance was below the minimum cut-off value set in the preset. Possible reasons are:
  • There is a compatibility problem between the generator and external devices.
  • There is an internal problem in the generator.
• Rarely, such as in pediatric cases, the patient has low body impedance and there is no problem.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary and catheter receptacle flashes red for 5 seconds
	S = Ablation stop tone
		• If the catheter is connected through an additional system such as a navigation system, try replacing the system parts that are between the generator and the catheter, or connect the catheter directly to the generator.
		• If the problem persists, contact Customer Support.
		• It is not recommended, but if you know the reason for the low impedance and still want to perform an ablation, you can disable this cut-off by setting its value to **Off**. (See Section 6.3.3, Editing a Preset.)

Impedance spike cut-off		

• The impedance change exceeded the spike cut-off value set in the preset. Possible reasons are:
  • The ablation created a steam pop.
  • The catheter was pushed suddenly into the tissue.
  • The spike cut-off value is too low.
	Ablation Stop Reason
	V = and Ablation Summary and catheter receptacle flashes red for 5 seconds
	S = Ablation stop tone
		Consider possible clinical reasons.
		• If you suspect that there is no reason for the impedance to spike, try increasing the cut-off to avoid getting this message due to measurement noise.
		• If the problem persists, contact Customer Support.
		• If it is clinically appropriate, you can disable this cut-off by setting its value to **Off**. (See Section 6.3.3, Editing a Preset.)

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message ▪ Reasons	Indicators (V = Visual, S = Sound)	What To Do
Incompatible catheter cable		
▪ The catheter connection cables have an electrical identification component that the system uses to verify that an approved type of cable is being used. This alert appears when the system does not detect the identification data. Possible reasons are: ▪ The cable was not provided by or recommended by the manufacturer. ▪ The cable was damaged during re-sterilization. ▪ The cable is faulty. ▪ There is a system problem.	**Alert** V = and **Alarm** indicator turns on/orange S = none	▪ If using an incompatible catheter connection cable, replace it with a cable that was provided by or recommended by the manufacturer. ▪ If using a compatible catheter connection cable, replace it with a new compatible connection cable. ▪ If the problem persists, contact Customer Support.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Incompatible esophageal probe cable (*not applicable for the US and JP versions of the generator*)		

• The esophageal probe connection cables have an electrical identification component that the system uses to verify that an approved type of cable is being used. This alert appears when the system does not detect the identification data. Possible reasons are:
  • The cable was not provided by or recommended by the manufacturer.
  • The cable was damaged during re-sterilization.
  • The cable is faulty.
  • There is a system problem.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
		• If using an incompatible esophageal probe connection cable, replace it with a cable that was provided by or recommended by the manufacturer.
		• If using a compatible esophageal probe connection cable, replace it with a new compatible connection cable.
		• If the problem persists, contact Customer Support.

Indifferent electrode not detected		
• No indifferent electrode was detected. • A split indifferent electrode is connected to the generator but is not applied to the patient.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary and both indifferent electrode receptacles flash blue for 5 seconds S = Ablation stop tone	• If a split indifferent electrode is connected to the generator, apply it to the patient. • Disconnect the indifferent electrode from the generator, then reconnect it. Check all other connections to the indifferent electrode such as the connection between the cable and the electrode itself. • Plug the indifferent electrode into the other indifferent electrode receptacle on the front of the generator. Contact Customer Support even if the problem is resolved. • If the problem persists, use a different indifferent electrode or a different cable.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Insufficient irrigation		

• High (ablation) flow was stopped. Possible reasons are:
  • The **Stop** button on the pump was pressed.
  • The **Low (Standby) Flow** button on the pump was pressed.
  • The foot pedal on the pump was released.
	Ablation Stop Reason
	V = and Ablation Summary
	S = Ablation stop tone
		• Restart the flow.

Low fluid		
• The generator has calculated that the amount of fluid in the irrigation bag is low.	**Warning** V = and orange border around Irrigation Control icon flashes for 20 seconds S = Warning tone	• Check the fluid level. If it is low, change the bag and after the ablation, update the fluid bag size on the Irrigation Control screen. (See Section 6.3.10, Irrigation Control.)
Measurement integrity error		

• The generator has two independent measurement channels for critical parameters; this message will appear if the two channels do not agree. Possible reasons are:
  • The cable is faulty.
  • There is a compatibility problem between the generator and external devices.
  • There is an internal problem in the generator.
	Alert
	V = and **Alarm** indicator turns on/orange
	S = none
	Ablation Stop Reason
	V = Ablation Summary
	S = Ablation stop tone
		• Disconnect any devices connected to the ablation catheter or to the indifferent electrode that are not approved by the manufacturer.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message ▪ Reasons	Indicators (V = Visual, S = Sound)	What To Do
No low (standby) flow		
▪ An irrigated catheter preset is selected, the catheter temperature and the impedance indicate that the catheter is in the patient, but the pump is stopped.	**Warning** V = and orange border around Irrigation Control icon flashes for 20 seconds S = Warning tone	▪ Press **START Low Flow** on the generator's Irrigation Control screen or press **Low (Standby) Flow** on the pump to start the pump flowing at the low (standby) flow rate. (See Section 6.3.10, Irrigation Control.)
Power output too high		

▪ The generator was trying to deliver a power output that was beyond its intended capability. Possible reasons are:
  ▪ There is a compatibility problem between the generator and external devices.
  ▪ There is an internal problem in the generator.
	Ablation Stop Reason
	V = and Ablation Summary and catheter receptacle flashes red for 5 seconds
	S = Ablation stop tone
		▪ Disconnect any devices connected to the ablation catheter or to the indifferent electrode that are not approved by the manufacturer.
		▪ If the problem persists, try disconnecting any other devices connected to the patient that are not mandatory.
		▪ If the problem still persists, turn the generator off. Let it cool down for 5 seconds, then turn it on again.
		▪ Contact Customer Support even if the problem is resolved.

Pump door open		
▪ The pump door is open.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	▪ Close the pump door.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

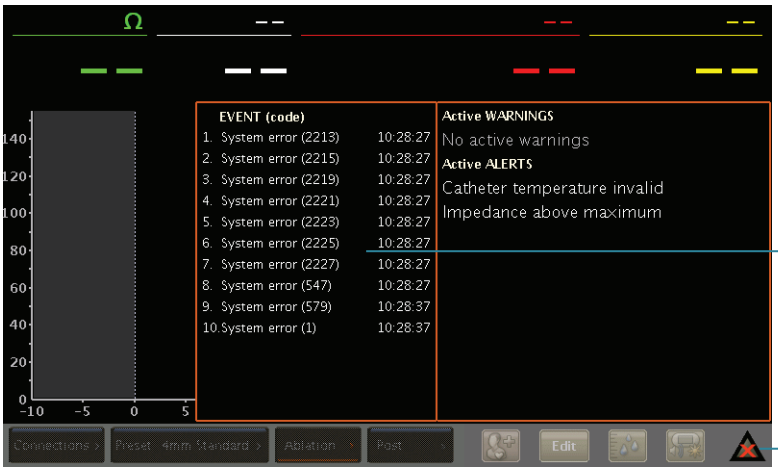
Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Pump error		
• There is an internal error in the pump.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	• See the Troubleshooting section in the user manual for the pump. • If the problem persists, contact Customer Support.
Pump not connected		
• An irrigated catheter preset is being used and no pump connection was detected.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	• If an irrigated catheter is being used, connect the pump to the generator. • If a non-irrigated catheter is being used, select an appropriate preset.
Remote disconnected		
• The remote control that had control of the generator is disconnected or there is a communication error between it and the generator.	**Warning** V = and orange border around System Control icon flashes for 20 seconds S = Warning tone **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	• Disconnect the remote control and operate the generator directly from the generator's user interface.
Stop button – Generator		
• The **Stop** button on the generator was pressed.	**Ablation Stop Reason** V = and Ablation Summary S = none	• To resume ablation, press **Ablation Start** or press and hold the foot pedal.

Table 8 – Warnings, Alerts, and Ablation Stop Reasons

Message • Reasons	Indicators (V = Visual, S = Sound)	What To Do
Stop button – Remote		
• The **Stop** button on the remote control was pressed.	**Ablation Stop Reason** V = and Ablation Summary S = none	• To resume ablation, press **Ablation Start** or press and hold the foot pedal.
System overheating		
• The internal hardware temperature of the system is too high.	**Alert** V = and **Alarm** indicator turns on/orange S = none **Ablation Stop Reason** V = Ablation Summary S = Ablation stop tone	• Make sure that the vents on the bottom and sides of the generator are not blocked. • Wait for a few minutes without turning on the RF energy and then try to operate the system again. • Contact Customer Support even if the problem is resolved.
Timer completed		
• The ablation time has reached the set value on the **ABLATION** screen.	**Ablation Stop Reason** V = and Ablation Summary S = none	• To resume ablation, press **Ablation Start** or press and hold the foot pedal.
Voltage output too high		
• The setup is causing the generator to deliver higher voltage than it was designed for.	**Ablation Stop Reason** V = and Ablation Summary and catheter receptacle flashes red for 5 seconds S = Ablation stop tone	• See the instructions in this table for **Power output too high**.

7.3 System Errors

Event Window Displaying System Error Codes



7.3.1 System Error

When a System Error occurs, the **System Status** icon is displayed and the Event window appears displaying the System Error codes.

The **Alarm** indicator is orange and the warning tone is emitted.

Manually record the codes displayed in the Event window. If you want to save the ablation files and event log, insert a USB flash drive containing a data transfer indicator into the back of the generator and wait for the data to transfer. Then press **Stand-by** for approximately 3 seconds to turn the generator off and press **Stand-by** again to turn the generator on. Contact Customer Support to report the codes, even if the problem is resolved.

7.3.2 Fatal System Error

The **Alarm** indicator flashes red and the high priority tone is emitted.

Immediately turn off the generator. If pressing **Stand-by** does not turn off the generator, remove the mains cable from the generator. Contact Customer Support.

7.4 Other Troubleshooting

Problem	What To Do
Bubbles are detected in the irrigation tubing during standby.	Immediately turn the 4-way stopcock on the SmartAblate™ Irrigation Tubing Set so that the fluid is not routed to the catheter. Then flush the tubing (see Section 6.6, Flushing to Eliminate Air in the Tubing and Catheter). After flushing, turn the 4-way stopcock to allow fluid to be routed to the catheter again.
On startup, the progress dots do not appear or the logo screen does not disappear.	Press and hold **Stand-by** for approximately 3 seconds to turn off the generator. Then press **Stand-by** again to turn the generator on. If the problem persists, contact Customer Support.
On startup, after you press **Stop** in response to the message that appears, the **ABLATION** screen does not appear.	Unplug the foot pedal and plug it in again. Then press and hold **Stand-by** for approximately 3 seconds to turn off the generator. Then press **Stand-by** again to turn the generator on. If the problem persists, contact Customer Support.
Nothing happens when you press a button on the screen.	See Section 7.5, Calibrating the Touch Screen.
The generator won't turn on.	Verify that the power supply meets the specifications in Section 8.1, Specifications and then check to see whether a fuse is broken. If a fuse is broken, replace it (see Section 4.5.3, Fuses). If the fuse is not broken or if a new fuse breaks, contact Customer Support.

7.5 Calibrating the Touch Screen

Over time, the buttons on the touch screen may move a little and the location that you press on the screen may no longer be exactly where the button is. If this happens, follow the steps below.

Quick Steps

- Press the **CONNECTIONS** workflow button.
- Press **System Settings**.
- Press **Calibrate Touch Screen**.
- Press each target after it appears (a total of 6 targets).
- Press **Stop**.

Notes

1. You can only calibrate the generator's screen when the generator is the system Master (see Section 6.7, System Control).
2. At any time during the calibration process, you can press **Stop** to exit calibration.
3. If the calibration is successful, you will see **Result:** . If the calibration is unsuccessful, you will see **Result:** . If the calibration is unsuccessful, repeat the steps until a successful calibration is achieved. If the problem persists, contact Customer Support.
4. When you perform calibration, be careful to press directly on the center of the target. If the calibration fails, try touching the center of the target with the tip of a pen instead of your finger.

8 Technical Data

8.1 Specifications

Impedance Unit

Measurement current	6.5 µA, 45 kHz sinusoidal
Measurement range	0...500 Ω ± max{5%, 3 Ω}, 1 Ω resolution
Indifferent electrode monitoring current	4 µA, 100 kHz sinusoidal
Measurement range	0...390 Ω ± 20%

Ablation Unit

Temperature	User configurable target: up to 90°C, 1°C increments User configurable cut-off: up to 95°C
Measurement range	10°C...60°C ± 1°C, 61°C…100°C ± 2°C (catheter) 10°C...50°C ± 1°C (esophageal probe) *(esophageal probe temperature is not available for US and JP versions)*
Preset time	Up to 999 sec, non-linear increments 5 to 30 sec
RF frequency	480 kHz ± 1 kHz
RF output	100 W / 100 Ω (version WW) 70 W / 100 Ω (versions JP and US) (software limits output depending on catheter type selected)
Measurement range	0...150 W ± max{8%, 2W} / (60-150 Ω)
RF maximum voltage	290 V ≈
Modes	Temperature Control Power Control (manually set power)

Interface

Interface	RS-232
	USB max. current 300 mA

Mains

Voltage	115-120 V / 230 V (versions US and WW) 100 V (version JP)
Frequency	50/60 Hz
Power consumption	350 VA

Fuses

T3.15 AH 250 V

Acoustic Error Signal

Sound pressure	Greater than 65 db(A)

Operational Limits

6 hour continuous operation with intermittent ablations

Maximum 75% of the time performing ablations at maximum of 100 W output

Maximum continuous ablation time at full power less than 30 minutes

Other

Classifications	Class I and defibrillation proof type CF (as defined in IEC/EN 60601-1) Class IIb (as defined in MDD 93/42/EEC) Class 3, FDA
Weight	18.5 kg
Dimensions	399 mm wide x 178 mm high x 344 mm deep
IP rating	IP21

8.2 Storage and Shipping Conditions

Ambient temperature	-30° to +65°C
Relative humidity	10% to 90% (non-condensing)
Atmospheric pressure	500 to 1060 mbar

8.3 Operating Conditions

Ambient temperature	10° to 40°C
Relative humidity	10% to 85% (non-condensing)
Atmospheric pressure	700 to 1060 mbar

8.4 ThermoCool® Catheter Preset Ranges

ThermoCool® Catheter

Power (W)	Pump Default (mL/min)
1…10	17
11…20	17
21…30	17
31…40	30
41…50	30

ThermoCool® SF Catheter

Power (W)	Pump Default (mL/min)
1…10	8
11…20	8
21…30	8
31…40	15
41…50	15

8.5 Alarm and Touch Specifications

After an alarm event occurs, there may be a delay of not more than 500 ms before the related sound, light, and/or message are produced.

All alarm events are recorded and stored in the SmartAblate™ RF Generator. If power is lost, alarm event data is maintained on the generator for a minimum of 30 days. This data can be exported (copied to a USB flash drive and deleted from the generator) by performing the steps in Section 6.5.1, Exporting Ablation and Event Log Data to a USB Flash Drive.

Alarm Tones and Alarm Indicator (AI) Light
(See Sections 7.2, Warnings, Alerts, and Ablation Stop Reasons and 7.3, System Errors.)

	Ablation Stop Reason	Warning, System Error	Fatal System Error
Comment	Information tone	Information tone	High priority alarm
Pulse Pattern	ti-ti	ti-ti	ti-ti-ti--ti-ti----------ti-ti-ti--ti-ti
Frequency	600 Hz	900 Hz	1000 Hz
Duration	600 ms	400 ms	4.2 s
Repetition	None	20 s	10 s
AI	Off	On, orange	Flashes, red, f = 2Hz, duty cycle 50%

Note: All alarms are technical alarms.

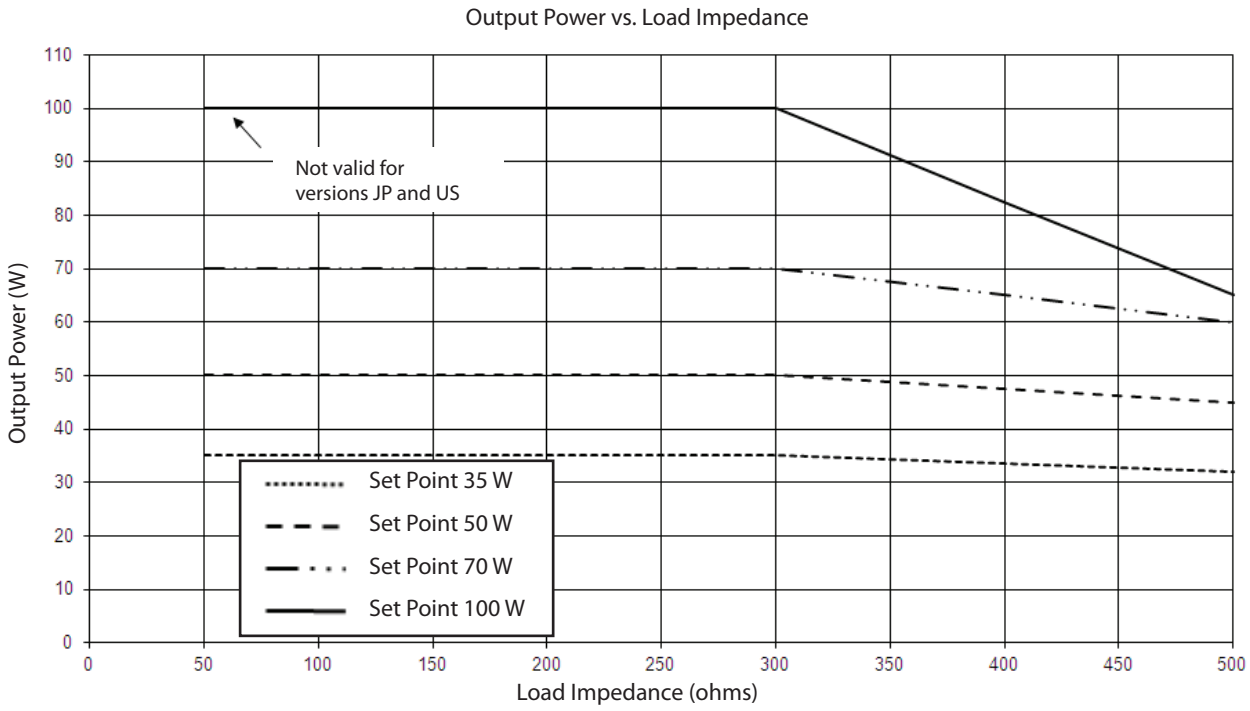
Signal Lights
(See Section 7.2, Warnings, Alerts, and Ablation Stop Reasons.)

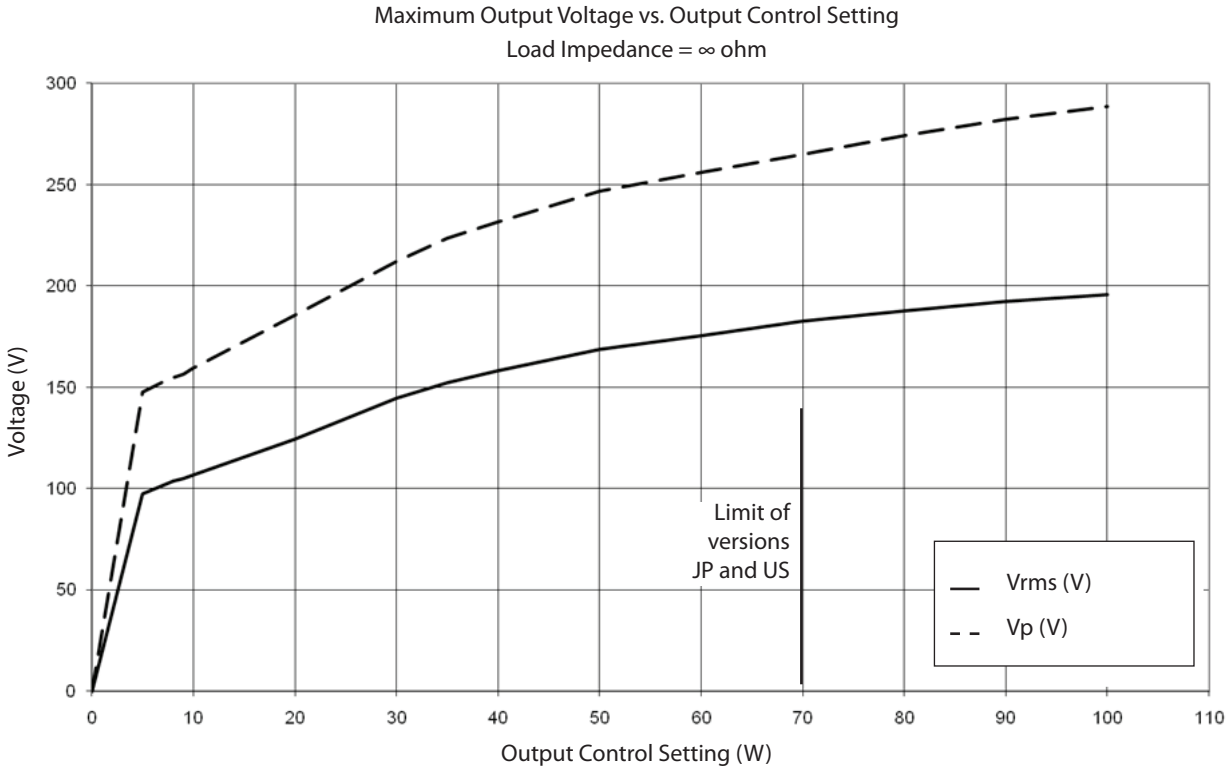
Indicator	Color	Frequency	Duration
Indifferent electrode receptacles	Blue	5 Hz	5 s
Catheter receptacle	Red	5 Hz	5 s
Esophageal probe receptacle *(not functional in the US or JP versions of the generator)*	Red	5 Hz	5 s
Border of System Control icon	Orange	0.5 Hz	Duration of warning
Border of Irrigation Control icon	Orange	0.5 Hz	Duration of warning
Border of System Status icon	Orange	0.5 Hz	Duration of warning

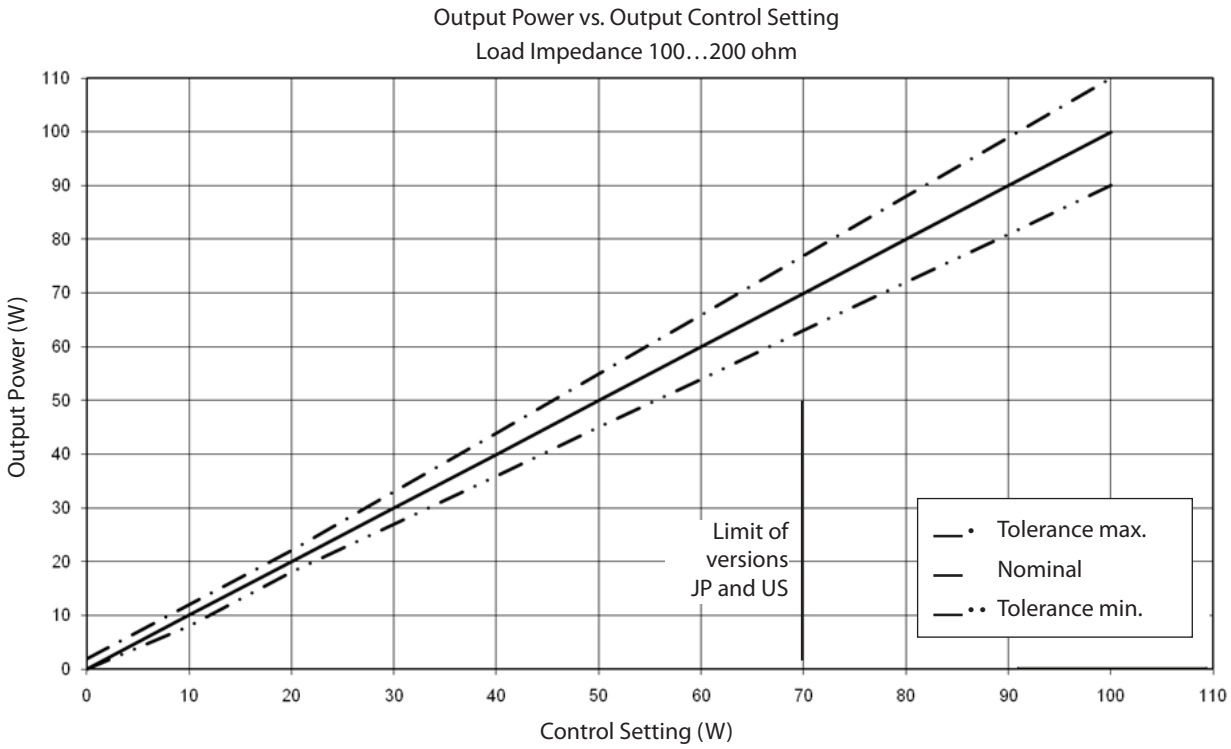
Touch Screen Tones

Event	Frequency	Duration
Touch is recognized and button is valid	4 kHz	40 ms
Touch is recognized but button or area is not valid	2 kHz	20 ms

8.6 Output Specifications







8.7 Safety Inspections

To ensure the safety of the SmartAblate™ RF Generator, inspect the generator before each use. Perform the following verifications.

- Verify that all of the visual and audible indicators available on the generator are functional (see Section 6.1.1, System Startup).
- Verify that preventive maintenance for the SmartAblate™ RF Generator is not overdue (see the description of the generator screen in Table 3 – Device Screens in Section 6.2, Connections).
- Verify that the **Data Entry Knob** is not loose and that the values on the screen change as expected when the knob is turned.
- Verify that the foot pedal is not damaged and that it functions correctly (see the description of the foot pedal screen in Table 3 – Device Screens in Section 6.2, Connections).
- Verify that the connections to all accessories are functional.

Once a year, perform the verifications listed above as well as those below.

- The device label is present and readable.
- The cable connection receptacles are not damaged and are not loose.
- The accessory cables (especially the mains cable and the grounding cables) are not damaged.
- The remote control can function as the system Master. (Make the remote control the system Master and then perform ablation using a STOCKERT test box for the SmartAblate™ RF Generator.)

Because the generator is a medical device, some countries require an electrical safety test. If local regulations require a safety test, have the generator tested by a technician certified by the local governing agency.

Important Notice

To ensure the safety of the SmartAblate™ RF Generator, repairs may be performed only by the manufacturer, a service engineer certified by the manufacturer, or a service center certified by the manufacturer. The safety inspections must be performed at least once a year, and after every repair, according to IEC/EN 60601-1 and its sub-standards and IEC/EN 62353.

8.8 Maintenance

Perform the safety inspections specified in Section 8.7, Safety Inspections.

Regularly clean and disinfect the SmartAblate™ RF Generator per Section 4.6, Cleaning and Disinfecting the Generator.

Regularly clean the accessories per the instructions for use provided with the accessories.

At least once a year, verify that the SmartAblate™ RF Generator and its accessories are installed per Section 4.5, Setup.

At least once a year perform the touch screen calibration per Section 7.5, Calibrating the Touch Screen.

The SmartAblate™ RF Generator contains measurement circuitry. To ensure that the generator stays in compliance with its performance specifications, the generator's calibration must be maintained. Every other year (and any time that loss of accuracy is suspected), contact Customer Support and schedule preventive maintenance that includes calibration and a full functional test. The calibration and the full functional test may be performed only by the manufacturer, a service engineer certified by the manufacturer, or a service center certified by the manufacturer.

At any time, if any problems are found, report them to Customer Support and send the generator or broken accessory for repair.

If desired, a service contract can be arranged. Contact Customer Support.

8.9 Repairs

There are no parts in the SmartAblate™ RF Generator that may be serviced by the user. (Exception: The fuses may be replaced per Section 4.5.3, Fuses.) Repairs or any changes to the generator and the accessories must be performed only by the manufacturer, a service engineer certified by the manufacturer, or a service center certified by the manufacturer.

8.10 Conformance to Standards

The SmartAblate™ RF Generator meets the requirements of the following standards.

Standard	Title
ANSI / AAMI HF-18	Electrosurgical devices
CAN/CSA C22.2 No. 601.1, B-90	Medical electrical equipment - Part 1: General requirements for safety
CMDR	Canadian Medical Devices Regulations
DIN EN 980	Symbols for use in the labeling of medical devices
DIN EN 1041	Information supplied by the manufacturer of medical devices
DIN EN ISO 14971	Medical devices - Application of risk management to medical devices
EU Dir. 2002/96/EC	EU Directive 2002/96/EC of 27 January 2003 on waste electrical and electronic equipment (WEEE)
EU Dir. 2006/66/EC	Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC
IEC 60812	Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)
IEC/EN 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC/EN 60601-1-1	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
IEC/EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC/EN 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical systems
IEC/EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC/EN 60601-1-8	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC/EN 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
IEC/EN 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC/EN 62304	Medical device software - Software life cycle processes

Standard	Title
IEC/EN 62353	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
IEC/EN 62366	Medical devices - Application of usability engineering to medical devices
MDD 93/42/EEC / MPG (Medical Products Law)	Medical Device Directive (MDD) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety

8.11 EMC Information and Technical Description

The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables approved by the manufacturer of the SmartAblate™ RF Generator as replacement parts for internal components, may result in increased emissions or decreased immunity of the SmartAblate™ RF Generator.

Electromagnetic Emissions

The SmartAblate™ RF Generator is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ RF Generator should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The SmartAblate™ RF Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The SmartAblate™ RF Generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

The SmartAblate™ RF Generator is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ RF Generator should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartAblate™ RF Generator requires continued operation during power mains interruptions, it is recommended that the SmartAblate™ RF Generator be powered from an uninterruptible power supply. Note that a 5 second removal of power, as tested, results in the device shutting down and requires user intervention to restart. There was no interruption of operation for other tests.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC mains voltage prior to application of the test level. The SmartAblate™ RF Generator was tested at 100 and 230 VAC.

Electromagnetic Immunity

The SmartAblate™ RF Generator is intended for use in the electromagnetic environment specified below. The customer or user of the SmartAblate™ RF Generator should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the SmartAblate™ RF Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17\sqrt{P}$ 150 kHz to 80 MHz $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartAblate™ RF Generator is used exceeds the applicable RF compliance level above, the SmartAblate™ RF Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SmartAblate™ RF Generator.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the SmartAblate™ RF Generator

The SmartAblate™ RF Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the SmartAblate™ RF Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartAblate™ RF Generator as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

EMC Information and Technical Description

MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this user manual.

Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

⚠ Warning: The use of ACCESSORIES, transducers, and cables other than those specified, with the exception of transducers and cables approved by the manufacturer of the SmartAblate™ RF Generator as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the SmartAblate™ RF Generator.

⚠ Warning: The SmartAblate™ RF Generator may be operated in the immediate vicinity of the SmartAblate™ Irrigation Pump. However, do not operate the generator in the immediate vicinity of devices that are not approved for electromagnetic compatibility (EMC) with the generator. If such operation is unavoidable, regularly monitor the generator to ensure proper functioning.

⚠ Warning: The SmartAblate™ RF Generator may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

The SmartAblate™ RF Generator internally generates RF electromagnetic energy for the purpose of its operation. The following frequency bands are used:

- 45 kHz ± 1 kHz is used for impedance measurement between the catheter and the indifferent electrode.
- 480 kHz ± 1 kHz is used for impedance measurement between the catheter and the indifferent electrode.
- 100 kHz ± 1 kHz is used for impedance measurement of the split indifferent electrode.

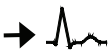
ECG signals have very small amplitudes (0.1 mV). For this reason, the SmartAblate™ RF Generator uses a sensitive measurement unit for the ECG signals. This measurement unit is also sensitive to externally radiated RF energy and can be disturbed by other systems placed close to the SmartAblate™ RF Generator. Possible sources of interference are, for example, neon lamps and power transformers.

The following instructions must be followed to avoid disturbance of the measurement quality:

- The SmartAblate™ RF Generator may be operated only with cables provided by or recommended by the manufacturer.
- The SmartAblate™ RF Generator must be connected with the grounding cable to a separate grounding point.
- All devices in the patient area that are connected to the SmartAblate™ RF Generator must be on the same mains.
- All devices in the patient area that are connected to the SmartAblate™ RF Generator must be connected to separate ground points with their own grounding cables.

See Section 5.1, Diagram of the Generator and Accessories, for an illustration of the typical configuration and the cables required for undisturbed measurement quality.

9 Symbols

Symbol	Description
Distributed by	The device is distributed by
Manufactured by	The device is manufactured by
	Quantity
	Catalog number
	Alarm
	Rotational adjustment. Clockwise rotation increases value.
	Follow operating instructions.
	Follow operating instructions.
	Upper and lower temperature limits (storage and shipping conditions)
	Upper and lower humidity limitation (storage and shipping conditions)
	Upper and lower atmospheric pressure limitation (storage and shipping conditions)
	Keep dry
	Caution
	To electrophysiology recording system (ECG)
	Press the button to release the lock and allow the front panel of the generator to be tilted up. *(not available on some models)*
	Indifferent electrode
	The indifferent electrode and catheter connections on the device have zero voltage. Connections identified with this symbol are floating (are not grounded).
	All patient connections of the device are defibrillation-proof type CF applied parts.
	Radiofrequency
	Potential equalization port
	Fuses

Symbol	Description
	Alternating current
	Serial data port
	Ethernet port
	Output signal
	Input signal
	USB port
	Remote control receptacle
	Foot pedal receptacle
	Pump receptacle
	Manufacturer
	Manufacturing date
	Serial number
	Lot number
	Japanese version of the SmartAblate™ RF Generator
	United States version of the SmartAblate™ RF Generator
	Worldwide version of the SmartAblate™ RF Generator (except the United States and Japan)
	Medical – applied current/energy equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1 / CAN/CSA C22.2 NO. 601-1 / IEC 60601-2-2 (2006) / ANSI/AAMI ES60601-1 (2005) / CAN/CSA C22.2 NO. 60601-1 (2008)/ IEC 60601-2-2 (2009) 40GF
	CE marking with the number of the notified body
	The device is radiating non-ionizing electromagnetic radiation. (See Section 8.11, EMC Information and Technical Description.)
	Separate collection for electrical and electronic equipment

Symbol	Description
	The device does not contain phthalates.
	The device is latex-free.
RoHS ✓	RoHS compliant (Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment)
	RoHS compliant (marking according to Chinese Administration on the Control of Pollution Caused by Electronic Information Product – ACPEIP - standard SJ 11364/2006)
IP 21	The device is protected against solid foreign objects of 12.5 mm diameter and greater and is protected against vertically falling water drops.
Made in Germany	Certificate of origin in Germany
HW-Rev.	Hardware revision number
DUTY CYCLE	Mode of operation: Indication of duty cycle giving the maximum activation (ON) time and the minimum deactivation (OFF) time.

10 Warranty

10.1 Transit Damage

The SmartAblate™ RF Generator and accessories must be examined for transit damage immediately after receipt. If the generator and accessories are damaged, notify Customer Support. Damage claims can be validated only if the seller or the shipping agent is informed immediately. For your convenience, an "Error Report" form is shipped with the generator; you can use this form to record any damage.

10.2 Warranty

The warranty for the SmartAblate™ RF Generator warrants that the generator will conform to its product specifications for a period of one year from the date of shipment or for the period of time defined in the purchase contract. The warranty does not cover normal wear and tear, damage due to improper handling, accessories, connection cables, and disposable parts. Repairs or any changes may be performed only by the manufacturer, a service engineer authorized by the manufacturer, or a service center authorized by the manufacturer. The warranty is voided if improper modifications or repairs are performed or if the device is not maintained according to the instructions in this user manual. The warranty is not extended or renewed by services performed under warranty.

10.3 Product Liability

Product liability is assumed by STOCKERT GmbH under the following conditions:

- The generator has been operated only with the original accessories provided by or recommended by the manufacturer (see Chapter 5, Accessories).
- Repairs to the generator and to the accessories have been performed only by the manufacturer, a service engineer authorized by the manufacturer, or by a service center authorized by the manufacturer.

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